European Directorate for the Quality of Medicines & HealthCare

60 YEARS ANS 2009

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

**24-25 April 2009**

# Optimal Clinical Use of Blood Components

PROCEEDINGS

*International Symposium co-organised by*
*the EDQM & HealthCare/DBO - Transfusion Medicine, Council of Europe*
*PEI, the German Official National Agency for Biologicals*
*The Transfusionsmedizin und Haemostaseologie, Klinikum der Universitaet Muenchen*

***Wildbad Kreuth**, Bavaria, Germany*

LMU KLINIKUM DER UNIVERSITÄT MÜNCHEN

Paul-Ehrlich-Institut

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LMU im Nov. 2010
in Vertretung von Dr. J-M. Spieser, EDQM und Prof. R. Seitz, PEI

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1. Auflage 2010

# Introduction to Kreuth Proceedings:

About 8 years after having organised a meeting of specialists from the, at that time 15 EU member states in Wildbad Kreuth (Bavaria) to exchange view points on possible ways to optimise the use of blood components, the organizers approached the EDQM to seek the possibility of getting experts together on a larger international scale. This continuation of the Kreuth initiative aimed at exchanging view points and gathering information in the field of therapeutical application of transfusion medicine, in order to make recommendations on how to optimise the clinical use of blood and blood components based on clinical evidence. The challenge was taken up by the LMU Munich and relevant Health Authorities, namely PEI and the EDQM who accepted to pool together their resources and experience to foster a successful meeting, and the basis for a new symposium in April 2009 was launched.

In order to prepare the participants for a fruitful discussion, a survey was launched prior to the Conference on the basis of the recommendations set up in the 1999 Kreuth meeting to query whether they were still acceptable, and which adaptation they might need in view of the changing environment.

We would wish to thank the Deutsche Ärztekammer (German Medical Association) who agreed to have their just finalised Cross-sectional Guidelines for Therapy with Blood Components and Plasma Derivatives translated into English; this document was used as a useful model for further elaborating on optimal clinical use of blood components and plasma derivatives, and access to these life saving products to all patients in need.

Finally, 110 experts from 38 countries accepted the invitation to meet in Kreuth again on 25-26 April 2009, to exchange their experiences with the aim to develop a consensus largely accepted internationally on the clinical use of blood components and to revisit the 1999 recommendations. The discussions were centred around four topics:

1. Blood products: red cells, platelets, fresh frozen plasma, albumin
2. Clotting factor concentrates and haemophilia treatment
3. Quality management in clinical use
4. Efficacy in terms of outcome including Health Technology Assessment and cost-effectiveness.

The present book represents the proceedings of the scientific presentations and the debates held during the workshops, their consensual conclusion and the final recommendations. The outcome is an updated appraisal of the state of the art, in view of an optimal clinical use of blood components and albumin and clotting factors which can be presented as an international reference, and will largely be distributed to relevant stakeholders including scientific and professional societies.

These proceedings will hopefully form the basis of further discussions at the level of the relevant National Authorities, but mainly European Institutions such as the EU Commission DG Sanco, and the Council of Europe/EDQM relevant scientific committees, and also beyond Europe, notably WHO.



Prof W. Schramm | Prof R. Seitz | Dr J-M. Spieser

# Programme

## European Symposium on "Optimal Clinical Use of Blood Components"
## April 24th-25th 2009, Wildbad Kreuth, Germany

**Friday 24 April 2009**

| | | |
|---|---|---|
| **8.00 – 10.00** | **Welcome** | EDQM- 5mn<br>BMG F. v. Auer- 5 mn<br>University of Munich<br>B. Göke- 5 mn |
| | **Challenges in Haemotherapy**<br>**Key elements and Rationale for the meeting** | W. Schramm- 10 mn<br>J.-M. Spieser- 10 mn |
| | **Status quo: Safety, supply vs. demand, regulations** | R. Seitz- 15-20 mn |
| | **Report on the EUOBUP project** | B. McClelland (tbc)- 10 mn |
| | **Guidelines for Haemotherapy: The German Approach** | P. Scriba- 5 mn<br>H. Klüter- 15 mn |
| 10.00 – 10.30 | Coffee Break | |
| **10.30 – 13.00** | **Different perspectives on optimal clinical use of blood components** | |
| | ***1. Blood products: red cells, platelets, FFP, albumin*** | |
| | • Transfusion services<br>• Clinicians | E. Seifried- 15 mn<br>H. Gombotz- 20 mn |
| | ***2. Clotting factor concentrates and haemophilia treatment*** | |
| | • Clinicians<br>• Patient organisations (WFH/EHC)<br>• Rare disorders | P. Giangrande - 15 mn<br>B. O'Mahony- 15 mn<br>F. Peyvandi- 15 mn |

***3. Quality management in clinical use***

- Transfusion services — E. Briet- 15 mn
- Clinicians: management of bleeding — M. Spannagl- 10 mn; M. Samama- 10 mn
- Education in Haemostasis — J. Astermark- 15 mn

13.00 – 14.00 Lunch

**14.00 – 15.10** ***4. Efficacy in terms of outcome***

- Transfusion services — C. van der Poel (tbc)- 15 mn; C. Politis (tbc)- 15 mn
- Clinicians:
  Health Technology Assessment; — A. Nimmo - 10 mn
  Clotting factor concentrates / Haemophilia — G. Minno - 10 mn

15.10 – 15.30 Coffee break

**15.30 – 18.45** ***Discussion in working groups***

- Working group 1 Blood products (Red blood cells, platelets, fresh frozen plasma and albumin)
- Working group 2 Clotting factor concentrates and haemophilia treatment
- Working group 3 Quality management in clinical use
- Working group 4 Efficacy in terms of outcome (including economical aspects)

20.00 ***Dinner***

**Saturday 25 April 2009**

**08.00 – 09.00** ***Plenary session: Interim reports from working groups***

**09.00 – 10.45** ***Discussion in working groups***

10.45 –11.00 Coffee break

**11.00 – 13.00** ***Plenary session: Final reports from working groups***

- Working group 1 Blood products (Red blood cells, platelets, fresh frozen plasma and albumin)
- Working group 2 Clotting factor concentrates and haemophilia treatment
- Working group 3 Quality management in clinical use
- Working group 4 Efficacy in terms of outcome (including economical aspects)

13:00 – 14:00 Lunch

**14:00 – 17:00** ***Plenary session: Conclusions and Recommendations***

European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

**Department of Biological Standardisation, OMCL-Network & HealthCare (DBO)**

**SYMPOSIUM ON**
**"OPTIMAL CLINICAL USE OF BLOOD COMPONENTS; QUALITY AND BEST PRACTICES IN HAEMOTHERAPY"**

**VENUE: Wildbad Kreuth – Bavaria – Germany - 24-25 April 2009**

## Participants list

## 24 – 25 April 2009

| Participant | Laboratory/Institute | Country |
|---|---|---|
| **ABU AMIN Noryati** | World Health Organisation (WHO) | Switzerland |
| **AGAFONOVA Zoya** | Burnazyan Federeal Medical Biophysical Center | Russian Federation |
| **AKESON Jonas** | Malmö University Hospital | Sweden |
| **ANDREEV Andrey Angelov** | National Center of Transfusion Haematology | Bulgaria |
| **AUVINEN Marja-Kaisa** | Finnish Red Cross – Blood Service | Finland |
| **AVALISHVILI Levan** | The Jo Ann Medical Centre | Georgia |
| **BAELE Philippe** | Cliniques Universitaires Saint Luc | Belgium |
| **BAGDATEVA Marina** | Clinical Hospital 119 of Federal Medico-biological Agency | Russian Federation |
| **BAROTINE TOTH Klara** | Hungarian National Blood Transfusion Service-Ministry of Health | Hungary |
| **BASTIDA Eva** | Plasma Proteins Therapeutics Association (PPTA) | Spain |
| **BEHR-GROSS Marie-Emmanuelle** | EDQM | |
| **BEIN Gregor** | Institut für Klin. Immunologie und Transfusionsmedizin | Germany |
| **BENSON Kaaron** | H. Lee Moffitt Cancer Center | USA |
| **BERGER Karin** | University Hospital of Munich | Germany |

| | | |
|---|---|---|
| **BOGDANOVA Vera** | Federal Medico Biological Agency | Russian Federation |
| **BRIËT Ernest** | Sanquin Blood Supply Foundation | Netherlands |
| **BUCHHEIT Karl Heinz** | EDQM | |
| **BURGER Reinhard** | Robert Koch-Institut | Germany |
| **CEBOTARI Svetlana** | National Blood Transfusion Centre | Moldova |
| **CHRONIDES Antonis** | Nicosia General Hospital | Cyprus |
| **CID Joan** | Hospital Universitario de Tarragona Juan XXIII | Spain |
| **CORDOBA Raul** | Hospital Infanta Sofia | Spain |
| **COURRIER Paul** | Centre de Transfusion sanguine de la Croix-Rouge | Luxembourg |
| **DAGBASHYAN Smbat** | Center of Heamatology and Blood Transfusion - Ministry of Health | Armenia |
| **DAVID Bernard** | Etablissement français du sang | France |
| **DE ANGELIS Vincenzo** | Trieste University Hospital-Transfusion Medicines | Italy |
| **DE WIT Jeroen** | Sanquin Blood Supply Foundation | Netherlands |
| **DHINGRA Neelam** | World Health Organisation (WHO)-Blood Transfusion Safety | Switzerland |
| **DI MINNO Giovanni** | Centro di Coordinamento regionale per le emocoagulopatie | Italy |
| **DOBROTA Alina Mirella** | Regional Centre for Blood Transfusion | Romania |
| **ERTUGRUL Nigar** | European Union Coordination Dept- Ministry of Health | Turkey |
| **ESPIRITO SANTO Deondile** | Hospital D. Estefania | Portugal |
| **FABBRIZZI Fabrizio** | Plasma Proteins Therapeutics Association (PPTA) | Italy |
| **FLESLAND Oystein** | Asker and Baerum Hospital | Norway |
| **GIANGRANDE Paul** | Oxford Haemophilia & Thrombosis Center | United Kingdom |
| **GOKE Burkhard** | Klinikum der Universität München | Germany |
| **GOMBOTZ Hans** | Allgemeines Krankenhaus der stadt Linz GmbH | Austria |
| **HARUTYUNYAN Hayk** | Center of Heamatology - Ministry of Health | Armenia |
| **HEIDEN Margarethe** | Paul Ehrlich Institut | Germany |
| **HEIN Marju** | Haematology and Oncology Clinic of Tartu University | Estonia |

| | | |
|---|---|---|
| **HOINARESCU Mihaela** | National Institute of Transfusion Haematology | Romania |
| **JOHANSSON Pär** | Blood Bank 2034 - Rigshsopiatlet | Denmark |
| **JURSEVICA Evelina** | Latvian State Blood Donor Centre | Latvia |
| **KARAKOC Imdat** | EU Coordination Dept - Ministry of Health | Turkey |
| **KAVALLIEROU-SIONI Garyfalia** | Blood Transfusion Centre, General Hospital Athens | Greece |
| **KLEIN Harvey** | National Institutes of Health – Clinical Center | USA |
| **KLUTER Harald** | Institut fur Transfusiosmedizin und Immunologie | Germany |
| **KORSAK Jolanta** | Military Institute of Medicine - Dept of Transfusiology | Poland |
| **KORTE Wolfgang** | Institut fur Klinische Chemie und Hamatologie | Switzerland |
| **LASPINA Stephan** | Mater Dei Hospital Blood Bank | Malta |
| **LESICKA-GORECKA Joanna** | Narodowe Centrum KRWI | Poland |
| **LEVY Guy** | Blood Transfusion Service of the Swiss Red Cross | Switzerland |
| **LIUMBRUNO Giancarlo Maria** | Italian National Blood Centre | Italy |
| **LOREK Malgorzata** | Narodowe Centrum KRWI | Poland |
| **LOZANO Miguel** | Hospital Clinic Provincial | Spain |
| **MACLENNAN Sheila** | NHS Blood and Transplant - Leeds Centre | United Kingdom |
| **MANSOURI Behrouz** | Inselspital Universitätsspital Bern | Switzerland |
| **MARANTIDOU Olga** | General Hospital Athens | Greece |
| **MASHAROVA Natalia** | National Institute of Haematology and Transfusiology | Bulgaria |
| **MC CLELLAND Brian** | Scottish National Blood Transfusion Service | United Kingdom |
| **MENITOVE Jay** | Community Blood Center of Greater Kansas City | USA |
| **MESAR Peter** | Klinika pediatrickej onkologie a hematoloogie - Children University | Slovak Republic |
| **MISKOVITS Eszter** | HNBTS | Hungary |
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| **NAUJOKAITE Alvyda** | Steering Committee of the National Program - Ministry of Health | Lithuania |
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| | | |
|---|---|---|
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| **O'CONNELL Niamh** | Hospital Consultant Haematologist | Ireland |
| **O'MAHONY Brian** | Irish Haemophilia Society | Ireland |
| **OSTERMANN Helmut** | Klinikum der Universitat Muenchen | Germany |
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| **PABINGER-FASCHING Ingrid** | Medizinische Universtat Wien | Austria |
| **PEERLINCK Kathelijne** | UZ Leuven – Hemophilia Centre | Belgium |
| **PETRINI Pia** | Karolinska Institute – Hospital | Sweden |
| **PEYVANDI Flora** | Universita degli Studi di Milano | Italy |
| **PLEYM Hilde** | St Olav University Hospital | Norway |
| **POLITIS Constantina** | Ministry of Health and Social Solidarity | Greece |
| **PROCHAZKOVA Renata** | Krajska Nemocnice Liberec | Czech Republic |
| **PUNAB Mari** | Tartu University Hospital | Estonia |
| **PUPELLA Simonetta** | Italian National Blood Centre | Italy |
| **RASOVIC Gordana** | Blood Transfusion Center - Clinical Center of Montenegro | Montenegro |
| **REBULLA Paolo** | Fondazione Ospedale Maggiore Policlinico | Italy |
| **REHACEK Vit** | Fakultni Nemocnice Hradec Kralove | Czech Republic |
| **REMEIKIENE Diana** | Kaunas Medical University Clinics | Lithuania |
| **RIVERA José** | Centro de Transfusion de Murcia | Spain |
| **ROSOCHOVA Jana** | National Transfusion Service of Slovak Republic | Slovak Republic |
| **SAMAMA Marc** | Hotel-Dieu University Hospital | France |
| **SAMARDZIJA Marina** | Clinical Hospital Osijek – Dept of Transfusion Medicine | Croatia |
| **SCHENNACH Harald** | Zentralikinstitut für Bluttransfusion | Austria |
| **SCHRAMM Wolfgang** | Klinikum der Universitaet Muenchen | Germany |

| | | |
|---|---|---|
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| **SEIFRIED Erhard** | DRK – Blutspendedienst Hessen | Germany |
| **SEITZ Rainer** | Paul Ehrlich Institut | Germany |
| **SERBAN Margit** | University of Medicine and Pharmacy Victor Babes | Romania |
| **SONDAG-Thull Danielle** | La Croix-Rouge de Belgique | Belgium |
| **SPANNAGL Michael** | University Hospital of Munich | Germany |
| **SPIESER Jean-Marc** | EDQM | |
| **STEINERTE Anna** | Latvian State Blood Donor Centre | Latvia |
| **STRAUSS-PATKO Maja** | Croatian Institute of Transfusion Medicine | Croatia |
| **TRINKAUS Miha** | Zavod Za Transfuzijsno Medicino | Slovenia |
| **VAKKURI Anne** | Helsinki University Central Hospital | Finland |
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| **VASILJEVIC Nada** | National Coordinator of the National Blood Transfusion | Serbia |
| **VELATI Claudio** | General Hospital of Sondrio | Italy |
| **VON AUER Friedger** | Bundesministerium fur Gesundheit | Germany |
| **VON HOEGEN Ilka** | Plasma Proteins Therapeutics Association (PPTA) | Belgium |
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| **WELTE Martin** | Institut fur Anaesthesiologie, Operative intensivmedisin und Schmerztherapie | Germany |
| **ZWAGINGA Jaap Jan** | Leids Universitair Meedisch Centrum | Netherlands |

# General enquiry in preparation of the European Symposium "Optimal Clinical Use of Blood Components"

# General enquiry in preparation of the European Symposium "Optimal Clinical Use of Blood Components"

## April 24th – 25th 2009, Wildbad Kreuth, Bavaria, Germany

Optimal use of blood and blood products is a postulate from clinical, ethical, moral, and social perspectives. 15 years after publication of the Sanguis study [1], apparently still large variations in blood usage exist despite the publication of numerous guidelines and reports on the optimal use of blood and its components.

Ten years ago a first milestone was set by the European Commission: The "Wildbad Kreuth Initiative" was a seminal meeting of experts from all member states of the European Union with the objective to explore existing practice, examine the literature, and provide recommendations for the implementation of optimal use of blood and blood products, as an element of a strategy for the European Union for blood safety and self-sufficiency. As major outcome of this initiative European recommendations have been published [2]. However since that time a tremendous number of new publications, new trends in treatment patterns and a growing focus on economic issues have changed the environment as compared to 1999.

As the World Health Organization stated, "Blood is an expensive and scarce resource. Unnecessary transfusion may cause a shortage of blood products for patients in real need." For the current century it can be anticipated that in most European countries the demand for blood and blood products will grow. The main reason for this is the demographic change towards ageing populations. Subsequently, the number of blood donations will decrease and the demand for blood products will grow with increasing morbidity and need for invasive procedures.

Discussing optimal use means talking about the right blood product for the right patient at the right moment, and to ensure appropriate documentation (Wildbad Kreuth Initiative 1999, of Conclusion No. 71). Transparency of treatment patterns, outcome and health economic data support the provision of optimal treatment and addresses also the economic concern from providers' and financial supports' perspective. Best practice in haemotherapy leads to avoidance of overuse, underuse, and inappropriate use.


[1] Use of blood products for elective surgery in 43 European hospitals. The Sanguis Study Group. Transfusion Medicine 1994; 4 (4): 251-268.

[2] Blood safety in the European Community: An initiative for optimal use.1999. Edt. W Schramm, R. Seitz, F. v. Auer. ISBN: 3-00-005705-6.

The second Symposium in Wildbad Kreuth will be largely sponsored by the European Directorate for the Quality of Medicines & Healthcare (EDQM) and will considerably broaden the scope beyond the EU member states of 1999, as members from almost all european countries are invited.
To prepare this meeting and ensure focused and fruitful discussions, it is deemed necessary to perform a survey on the actual status in the participating countries, in order to have a more precise idea about their supply situation, current practice and strategic needs are. The objective of the following questionnaire is to obtain country specific information on elements of the national health care structure and how they may influence best practice care/optimal use of blood.

The information gathered will remain confidential and any report or document worked out of this enquiry will be anonymised if so wished or required.

All data collected for the survey will be transferred securely to EDQM, will not be used for any other purpose whatsoever, and will be securely archived after the data has been successfully received and confirmed by EDQM.

We kindly ask you to answer the questions based on your individual national background and experiences in the area of blood usage.

We would greatly appreciate if you could complete the questionnaire either:

- directly online, using the following link http://www.wildbad-kreuth-2009.de (using the User Name & Password provided separately), or
- complete the questionnaire on your computer in PDF form on this document, and return it as an email attachment, or
- print out the questionnaire, complete it, and return it by fax.

Deadline April 8th: Completion of online questionnaire, or return by email, or send by fax.

**EDQM – European Directorate for the Quality of Medicines & Healthcare**
**Jean-Marc SPIESER**
**Head of DBO, EDQM, Council of Europe**

By Mail: Ahlem.Sanchez@edqm.eu (by preference)

or by Fax: +33 (0) 3 88 41 27 71

Thank you very much for your well appreciated contribution!
We look forward to welcoming you in Wildbad Kreuth on April 24th–25th 2009.

**Prof. Dr. Wolfgang Schramm** **Prof. Rainer Seitz** **Jean-Marc Spieser**

The information reported in this questionnaire will remain confidential and any report or document worked out of this enquiry will be anonymised if so wished or required.

If needed, please do not hesitate to add extra pages for your comments, if the space allowed is insufficient. Please then indicate in the relevant item that you have attached extra pages. (Please use .doc or .pdf format.)

*For evaluation purposes we kindly ask you to give us the following background information:*

Please indicate for what country the information is given _____

What is your professional background:

- ☐ Transfusion service
- ☐ Clinician in daily clinical routine care
- ☐ Governmental / Regulatory Authority

## 1. Guidelines

*Do you use international recommendations or guidelines for the clinical use of blood products?*

☐ Yes ☐ No

☐ Council of Europe

☐ Other (please indicate origin) _____

*Do you use any specific national guidelines for clinical use of blood products?*

☐ Yes ☐ No

Guidelines, Issuing Institution, Year: Please could you attach a copy of these guidelines to this questionnaire _____

**Do these specific national guidelines cover:**

| | | |
|---|---|---|
| Blood product (red blood cells, platelets, fresh frozen plasma, albumin | ☐ Yes | ☐ No |
| Clotting factor concentrates and haemophilia treatment | ☐ Yes | ☐ No |
| Quality management in clinical use | ☐ Yes | ☐ No |

**Are these specific national guidelines regularly updated?** ☐ Yes ☐ No

**Do you consider guidelines useful for the daily routine practice?** ☐ Yes ☐ No

Comments: _____

## 2. Quality Management in clinical use of blood products

*Clinical Decision making process: Who decides usually in clinical daily routine use on blood product usage?*

**Operating Theatre**

- ☐ Anesthesiologist
- ☐ Surgeon
- ☐ Transfusion/Haemostasis specialists
- ☐ Other Specialist
- ☐ Others _____

**Ward/Intensive care unit**

- ☐ Anesthesiologist
- ☐ Surgeon
- ☐ Transfusion/Haemostasis specialists
- ☐ Other Specialist
- ☐ Specialist in internal medicine
- ☐ Others _____

*Does your health care system collect quantitative information about the use of blood products?*

☐ Yes ☐ No

**Where is this information documented?**

National registry ☐

National providers ☐

Others _____

Comments: _____

*Do you have tracer operations like hip replacement or myocardial revascularization to control the use of blood products?*

☐ Yes ☐ No

- ☐ Hip replacement
- ☐ Myocardial revascularization
- ☐ Others _____

*Do you have any special regulation concerning for the use of blood products?*

☐ Yes ☐ No

*Do you have dedicated responsibilities for blood transfusion within the hospitals?*

☐ Yes ☐ No

**Do you operate a quality management systems for clinical blood usage?**

☐ Yes ☐ No

**Are the hospitals required to develop standard operating procedures?**

☐ Yes ☐ No

*Do you have a structured education for people involved in transfusion?*

☐ Yes ☐ No

*Do you consider it as important to assess efficacy / outcomes of transfusion?*

☐ Yes ☐ No

**What is the parameter of success?**

- ☐ Laboratory parameters
- ☐ Outcomes in terms of morbidity
- ☐ Outcomes in term of mortality
- ☐ Others _____

## 3. Provision of blood products in your country

*Who are the main providers of blood products in your country?*

| Provider | National | Private | Other | % of supply |
|---|---|---|---|---|
| _____ | ☐ | ☐ | ☐ | _____ |
| _____ | ☐ | ☐ | ☐ | _____ |
| _____ | ☐ | ☐ | ☐ | _____ |

*Do you encounter periods of shortage of blood products?*

| | | |
|---|---|---|
| **Red Cells** | ☐ Yes | ☐ No |
| **Platelets** | ☐ Yes | ☐ No |
| **Fresh Frozen Plasma** | ☐ Yes | ☐ No |
| **Albumin** | ☐ Yes | ☐ No |
| **Factor VIII** | | |
| **Plasma-derived** | ☐ Yes | ☐ No |
| **Recombinants** | ☐ Yes | ☐ No |
| **Factor IX** | | |
| **Plasma-derived** | ☐ Yes | ☐ No |
| **Recombinants** | ☐ Yes | ☐ No |

*Analyzing the actual trends, how will these trends influence the supply and provision of blood products in the next years?*

- ☐ Shortage
- ☐ Price increase
- ☐ Structural changes

*What do you expect from health policy and regulatory institutions e.g. national authorities, EU/EDQM/WHO?*

_____

_____

*What are your priorities for the next years to achieve optimal provision of blood products?*

_____

_____

*How are blood products reimbursed in clinical care?*

- ☐ Reimbursement is provided through a lump sum or DRG
- ☐ Blood products are separately reimbursed
  - ☐ fully reimbursed
  - ☐ partial reimbursed
  - ☐ special: _____
- ☐ Complete different modus of reimbursement, please specify:

_____

_____

*Are there any patient co payments for blood products?*

☐ Yes ☐ No

*What is the **average** price for blood products in your country? (indicate)*

| | | |
|---|---|---|
| **Red Cells** | _____ | Euro per Unit |
| **Platelets** | _____ | Euro per Unit |
| **Fresh Frozen Plasma** | _____ | Euro per Unit |
| **Albumin** | _____ | Euro per Unit |
| **Factor VIII** | | |
| **Plasma-derived** | _____ | Euro per Unit |
| **Recombinants** | _____ | Euro per Unit |
| **Factor IX** | | |
| **Plasma-derived** | _____ | Euro per Unit |
| **Recombinants** | _____ | Euro per Unit |

# BLOOD SAFETY IN THE EUROPEAN COMMUNITY: AN INITATIVE FOR OPTIMAL USE WILDBAD KREUTH, GERMANY

## 20–22 MAY 1999

Please find below the recommendations from the first Wildbad Kreuth Initiative, 1999.
We kindly ask you to give us feed back from your actual perspective if these earlier recommendations have been achieved, if they are still obsolete or if they have to be rediscussed and revised.
Further we are interested in the grade of priority of each of these earlier issued recommendations.

## Chapter: Recommendations (No 97–150, p. 3–49)

### 3.1. RED BLOOD CELLS

#### 3.1.1. Supply

97. Reduction of inappropriate blood use should help to minimise the incidence and severity of blood shortages. Consideration should be given to establishing a blood exchange programme in the European Community. Hospital inventory management should be optimised and should include the use of blood ordering schedules.

*Grade of priority of this recommendation*
Please indicate from your opinion:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

*1 = lowest priority, 5 = highest priority*

*Actual perspective 2009*

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

98. An EC blood exchange programme could be envisaged as a single office serving as a central co-ordinating base matching shortages and available stock in different blood centres.
Such networks exist with varying success in several European centres. A pilot project would be necessary to assess whether the system would be useful or effective.

*Grade of priority of this recommendation*
Please indicate from your opinion:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

*1 = lowest priority, 5 = highest priority*

*Actual perspective 2009*

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

### 3.1.2. Residual risk

99. Introduction of new strategies to improve transfusion safety should be prioritised on the basis of achievable safety gains. Optimising blood transfusion practices could be much more effective in terms of health gain and cost benefit than additional testing strategies.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

100. The administrative practices related to transfusion, including recipient identification and compatibility testing, vary widely in the Community. The basis for and the benefits of these differences need to be critically reviewed. Mortality and morbidity from ABO mismatch remains a very serious problem throughout the Community, and is probably far greater than any residual virus risk. Effective systems that reduce this risk to zero must be identified and adopted particularly at the hospital level.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

101. Certain definite indications for leucodepletion are generally agreed and implemented. Where leucodepletion is required it should be performed in a controlled fashion in a blood centre or facility, and in an optimum relation to the time of donation so as to minimise any risk of bacterial proliferation.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

### 3.1.3. Efficacy

102. Patients require a product that has maximum oxygen delivery capability and minimised risk. As optimum storage time and conditions as defined by clinical utility have never been determined they need to be urgently addressed.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

### 3.1.4. Inappropriate use

103. Every hospital undertaking blood transfusion must have a quality management system in place, that includes a designated and specially trained individual with responsibility for the quality of transfusion practice in the hospital and that includes a systematic programme of ongoing education and a documented and systematic approach to clinical audit. This system of clinical audit should use accepted specified audit measures uniformly adopted throughout the Community (to be specified) and a standardised, published audit report format, with published annual reports.

***Grade of priority of this recommendation***
Please indicate from your opinion:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

104. Appropriate blood conservation programmes should be in use in every hospital.

***Grade of priority of this recommendation***
Please indicate from your opinion:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

105. Attention should be given to the development of effective education programmes in transfusion at undergraduate and postgraduate level.

***Grade of priority of this recommendation***
Please indicate from your opinion:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

106. There is an urgent need for well-designed large-scale studies in blood transfusion in surgical patients, both adult and paediatric, to provide even quite basic outcome data. These studies could be organised and funded on a Community level.

***Grade of priority of this recommendation***
Please indicate from your opinion:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

## 3.2. PLATELETS

### 3.2.1. Products and their availability

107. Platelet products should be prepared and stored so as to maintain maximal therapeutic outcome and minimise untoward effects.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

108. Concerning availability, there is an urgent need to evaluate the impact of possible delays throughout the platelet transfusion chain as well as the cost-effectiveness of platelet transfusion therapy resulting from the introduction of NAT testing. Blood services should be organised in such a way so as to:

– minimise temporary and other possible shortages, e.g. rare phenotype platelets (collaboration between Member States may contribute to success in this respect); and

– minimise the wastage of products without compromising the quality of platelet concentrates.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

109. The implementation of NAT tests should enable the release of platelet concentrates preferably in less than 24 hours after donation.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

### 3.2.2. Indications and platelet transfusion threshold levels

110. The clinical decision to transfuse platelets should be based on careful evaluation of the individual patient's condition, including bleeding history, bleeding tendency, in addition to actual platelet count or any laboratory result reflecting platelet function.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

111. To support clinical decision making, it is strongly recommended that an algorithm for defining transfusion needs be developed. Such algorithms should be developed and implemented through the cooperative efforts of clinical and transfusion medicine specialists, and be subject to regular review.

***Grade of priority of this recommendation***
Please indicate from your opinion:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

### 3.2.3. Dosage and efficacy

112. The outcome of platelet transfusion in terms of corrected platelet increment (CCI), for example, should be evaluated as a basis for improved transfusion practice. This involves assessing platelet recovery (or CI), actual increase in platelet count, and time (days) between two transfusions.

***Grade of priority of this recommendation***
Please indicate from your opinion:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

113. It is recommended that research on developing better techniques to monitor the efficacy of platelet transfusion be supported.

***Grade of priority of this recommendation***
Please indicate from your opinion:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

### 3.2.4. Refractoriness

114. Efforts should be made to prevent alloimmunisation in patients who are expected to be given repeated platelet transfusions by using products known to be less immunogenic such as leucocyte depleted cellular blood components.

***Grade of priority of this recommendation***
Please indicate from your opinion:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

### 3.2.5. Quality aspects and haemovigilance

115. Development of algorithms in the appropriate use of platelet concentrates, in addition to the establishment of haemovigilance systems, is advocated as part of a quality system. The efficacy of platelet transfusion as well as the associated side effects should be assessed. Parameters on transfusion out-come should be registered and evaluated within an appropriate healthcare quality system.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

## 3.3. FRESH FROZEN PLASMA

116. For improved safety, FFP products that have been quarantined or virus attenuated should be used.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

117. The clinical and biological results of FFP infusion should be monitored since there are different FFP qualities available and the individual response of the patients with coagulation disorders may be variable.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

118. Since the intended benefit of FFP is the correction of coagulation disorders, tests that assess the haemostatic functions and provide results rapidly are essential for its optimal use. This implies the permanent availability of a laboratory to perform coagulation tests.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

119. The duration of therapy should be determined by clinical evaluation and serial determination of coagulation parameters.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

120. The numerous existing guidelines should be harmonised. Their dissemination and implementation should be strongly reinforced by quality assurance systems. As a possible way to improved application, summarised guidelines should be included on prescription forms and their impact should be measured.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

121. The education of medical personnel should be improved.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

## 3.4. ALBUMIN

122. The existing evidence from published clinical studies addressing albumin use is insufficient. A convincing elaboration of benefits of albumin with respect to measurable clinical endpoints in comparison to other colloids will need substantially augmented evidence by further well-designed clinical studies.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

123. Since a potential deleterious effect of albumin infusion has been highlighted in the Cochrane Injuries Group Albumin Reviewers meta-analysis, further studies on mortality are required.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

124. The impact of preparations with different albumin concentrations and their respective sodium content is unresolved and should be studied further with respect to clinical efficacy and economic consequences.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

## 3.5. CLOTTING FACTOR CONCENTRATES

125. In order that future requirements for expensive blood products within the European Community can be assessed, registers of patients with haemophilia and related disorders should be established and maintained in each Member State of the Community.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

126. A haemovigilance or pharmacovigilance programme should be established in the Community, in cooperation with each Member State, to gather information on such patient complications as inhibitor development, allergic reactions, viral transmission and other miscellaneous adverse events.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

127. A network of Comprehensive Care Centres should be established within each Member State, in accordance with common criteria, which would provide 24-hour clinical and laboratory service and be accessible to all patients.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

128. Adequate amounts of coagulation factor concentrates for the treatment of patients with haemophilia and related disorders should be available in each Member State. Quantities of both plasma--derived and recombinant products should be maintained, although it is recognised that recombinant products could gradually supplant plasma-derived ones. Individual patient preferences should be taken into consideration when choosing products.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

129. Particular attention needs to be taken by the European Community on the possible adverse consequences should a monopoly for the production of coagulation factor concentrates emerge. Research on the development of emerging recombinant technologies in the Community needs to be encouraged and funded.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

130. The numerous guidelines from medical bodies in the various Member States should be harmonised and expanded to include advice on dosages for the treatment of common spontaneous bleeding problems.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

131. As a general rule, prophylactic treatment for children with severe haemophilia is recommended.

***Grade of priority of this recommendation***
Please indicate from your opinion:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

132. Immune tolerance should be offered to all patients with haemophilia who develop new inhibitory antibodies.

***Grade of priority of this recommendation***
Please indicate from your opinion:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

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***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

133. The outcome of treatment, including parameters related to quality of life and economic aspects, still needs to be assessed, and further studies, which will require funding, should be initiated.

***Grade of priority of this recommendation***
Please indicate from your opinion:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

## 3.6. QUALITY MANAGEMENT

134. There is an urgent need to foster the commitment of decision makers, both at national and local levels, to establish a Quality Management System within hospitals for the clinical use of blood products

***Grade of priority of this recommendation***
Please indicate from your opinion:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

135. There is the need to ensure that:
- A quality manager for clinical use of blood products is appointed and empowered to take appropriate actions to ensure and improve quality, in co-operation with the hospital transfusion committee; and
- The quality manager, along with the transfusion committee, should be responsible for defining and disseminating guidelines and SOPs for optimal use of blood products, and verifying their application by the healthcare professionals.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

136. There is the need to ensure that:
- Strategies are developed to maximise the cooperation of all healthcare professionals in the achievement of optimal use of blood products.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

137. There is an urgent need to:
- Carry out controlled studies to define the appropriate use for blood products and the parameters needed to evaluate their efficacy and outcome;
- Document the indications for the use of blood products on the request form; and
- Define a limited number of common indicators in order to allow comparison between different hospitals and increase awareness of inappropriate use.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

138. There is an urgent need to foster:
- A continuing education programme for healthcare professionals involved in the clinical use of blood products organised by the transfusion committee; and
- Inclusion of transfusion medicine in undergraduate and postgraduate training.

***Grade of priority of this recommendation***
Please indicate from your opinion:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

139. In defining SOPs, particular attention should be given to preventing transfusion errors, re-engineering the process, and introducing, if possible, information instruments, such as portable barcode readers, to assess the identity of the patient, the blood samples and the assigned unit.

***Grade of priority of this recommendation***
Please indicate from your opinion:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

140. The establishment of an integrated hospital information and documentation system is strongly recommended, since this could greatly facilitate the collection and analysis of data related to the use of blood products.

***Grade of priority of this recommendation***
Please indicate from your opinion:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

## 3.7. ECONOMIC ASPECTS

### 3.7.1. Information needs

141. The epidemiology of blood and blood product use should be assessed in the European Community to determine the likely clinical need and assist in planning future provision.

***Grade of priority of this recommendation***
Please indicate from your opinion:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

142. Blood and blood product use for the treatment of patients with index conditions should be recorded for each Member State on an annual basis, to provide baselines and indicators for comparison.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

143. Consideration should be made for a linkage between product usage and the clinical conditions for which they are being used. This might be best achieved through the use of automated databases, the use of electronic patient records and electronic prescribing.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

144. Reviews of blood and blood product use should be conducted using economic as well as clinical measures to determine the patterns of usage, to ascertain appropriateness of use, and to assess the effect of education programmes. Indicators should be developed to reflect optimum usage.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

145. Consideration should be given to sponsoring these kinds of studies across the European Community.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

### 3.7.2. Future demands

146. It is recognised that there are changes underway in the relative use of plasma-derived albumin, immunoglobulins, Factors VIII and IX. This will have important consequences on the costs and availability of these products in the future. A study of the future demand and need for blood and blood products should be undertaken with appropriate assessment of the economic factors to determine the viability of blood collection and fractionation centres.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

147. Consideration should be given to the rational distribution of these centres throughout the European Community, their commercial viability and national dependency in the context of self-sufficiency.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

### 3.7.3. Education requirements

148. Undergraduate and post-registration education and training of all clinicians who use blood and blood products should be promoted. Ways of increasing the impact of clinical recommendations and guidelines should be investigated.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

### 3.7.4. General recommendation

149. Economic evaluation should underpin the drive to improve the efficiency of resourcing and optimal use of blood and blood products, while maintaining the principle of voluntary non-remunerated blood donation.

***Grade of priority of this recommendation***
Please indicate from your opinion:

*1* ☐ *2* ☐ *3* ☐ *4* ☐ *5* ☐

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

150. The principle and the need for self-sufficiency should be re-assessed in the context of safety, availability, ethics and economics, in view of the continuing development of the European Community.

***Grade of priority of this recommendation***
Please indicate from your opinion:

| *1* | *2* | *3* | *4* | *5* |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

*1 = lowest priority, 5 = highest priority*

***Actual perspective 2009***

☐ Still valid ☐ Achieved and implemented ☐ Obsolete ☐ To be rediscussed and revised

*Thank you very much!*

# Presentations

# Challenges in Haemotherapy

**Wolfgang Schramm**

# Key elements and Rationale for the meeting

**Jean-Marc Spieser**

# Status quo: safety, supply vs. demand, regulations

**Rainer Seitz**

# Optimal use of Blood

**Brian McClelland**

# Cross-sectional guidelines (BÄK) Therapy with blood components and plasma derivates

**Harald Klüter**

# Optimal use of blood components: The relevance of transfusion services

**Erhard Seifried**

# Optimal use of allogeneic blood products

**Hans Gombotz**

# Achieving consensus on optimal treatment of haemophilia

**Paul Giangrande**

# Haemophilia treatment in Europe – an overview

**Brian O'Mahony**

# Rare bleeding disorders

**Flora Peyvandi**

# Rational quality management

**Ernest Briët**

# Transfusion
# QM --- Clinical Management

**Wolfgang Korte**

# Education in Haemostasis

**Jan Astermark**

# The use of blood components and patient characteristics

**Cees L. van der Poel**

# Efficacy of transfusion services in term of outcome

**Constantina Politis**

# HTA – Clinical and cost effectiveness of thromboelastography / thromboelastometry

**Alastair Nimmo**

# Clotting factor concentrates Haemophilia

**Giovanni Minno**

# Discussion for the final Recommendations:

## DISCUSSION FOR THE FINAL RECOMMENDATIONS:

## Group 1 Rapporteur: E. Seifried

Group 1 dealt with the optimal use of blood products, particularly red blood cells, platelets, fresh frozen plasma and albumin. The new versions of the recommendations are listed below. Several new recommendations have been added, although most of the preceding versions have either been left unchanged or slightly modified (marked with *).

### General recommendations

Six fully new recommendations have been added (1 to 6 below).

Recommendation 1 emphasised the necessity that blood establishments should make every effort to forestall the problems presented by the increases in the demands for blood products, coupled to the aging of the population. It was felt that measures should be taken to increase the percentage of donors.

Recommendation 2 expressed the necessity of preparing plans for emerging pathogens, such as HIV. Alert systems and disaster plans were essential. This was clearly a response to problems in recent years.

Recommendation 3 expressed the need for evidence-based clinical guidelines throughout Europe. This is evidently compatible with the growing importance of evidence-based medicine.

Recommendation 4 proposed a European benchmark project, coupled to the identification of centres of excellence. One objective was to improve patient blood management.

Recommendation 5 expressed the need for improving training in transfusion medicine and proposed the development of a common curriculum. This was aimed at improving the expertise of professional workers in the field.

Recommendation 6 proposed the development of long-term biorepositories. This was intended to preserve reference samples.

### Red blood cells

One new recommendation (16) has been added and 7 other recommendations have been slightly rephrased (new numbers 7, 9, 10, 11, 12, 14 and 15).

Recommendation 10 now emphasises the risk of ABO mismatch.

Recommendation 16 proposes that blood establishments should analyse patterns of red blood cell use to minimise wastage.

**Platelets**

Six new recommendations have been added (new numbers 19, 20, 23, 27, 28 and 29) and 6 other recommendations have been slightly rephrased (new numbers 17, 18, 22, 24, 25 and 26).

Recommendation 19 mentions the possibility of using platelet-additive solutions when clinical equivalence has been demonstrated.

Recommendation 20 mentions the possibility of using novel platelet-derived products when there is adequate clinical data to support their use.

Recommendation 23 mentions the possibility of prophylactic treatment with platelet concentrates for patients with thrombocytopenia. The type of thrombocytopenia is not specified.

Recommendation 27 advocates that blood establishments in Europe should have the capability of diagnosing and managing the blood supply in different forms of thrombocytopenia.

Recommendation 28 advocates the use of methods to reduce the risk of bacterial contamination of platelet concentrates.

Recommendation 29 emphasises that the impact of ABO-incompatible platelet transfusion should be clarified.

**Fresh frozen plasma**

One new recommendation has been added (new number 36) and 4 other recommendations have been slightly rephrased (new numbers 30, 31, 32 and 33).

Recommendation 36 now advocates the precaution of using only male donors or female donors without a history of pregnancy, as this reduces the risk of immune TRALI.

**Albumin**

No changes have been made.

## Group 2 Rapporteur: P. Giangrande

Group 2 dealt with the optimal use of clotting factor concentrates. The new versions of the recommendations are listed below. Six new recommendations have been added (new numbers 43, 46, 49, 50, 51 and 52). A further 7 recommendations have been slightly modified (marked with *) - new numbers 39, 40, 41, 42, 130, 131 and 133. Recommendation 47 is unchanged.

Recommendation 43 proposes that a formal mechanism should be established in each country to develop best practice in haemophilia care.

Recommendation 46 supports the encouragement of home treatment with coagulation factor for patients with severe haemophilia.

Recommendation 49 proposes that family trees should be drawn up for patients with haemophilia and other inherited bleeding disorders. Genetic counselling should be offered.

Recommendation 50 states that awareness to rare bleeding disorders should be enhanced.

Recommendation 51 supports the use of specific coagulation factors for patients with rare bleeding disorders. Prophylaxis should be considered in patients with severe phenotype. The development of orphan drugs should be encouraged.

Recommendation 52 states that the development of equitable care in all member states should be fostered by the European Union.

## Group 3 Rapporteur: W. Korte

Group 3 dealt with quality management and clinical management. The new versions of the recommendations are listed below. Eight new recommendations have been added (new numbers 54, 55, 57, 58, 59, 62, 64 and 66). Recommendation 56 has been slightly modified. The other recommendations are unchanged.

Recommendation 54 suggests the implementation of so-called “clinical champion” status for persons with special expertise and experience in using blood components. Clinical champions should have a series of responsibilities, including educational activities, coordination between persons producing and persons using blood products, developing markers of efficacy and outcome, securing adherence to guidelines and detection of overuse or underuse of blood components.

Recommendation 55 states that implementation of transfusion quality is the responsibility of hospital management, possible in collaboration with a national committee.

Recommendation 57 proposes that quality management of blood components should be integrated within total quality management and general risk assessment in the respective institution.

Recommendation 58 proposes that national legislation or regulations should be modified to allow implementation of recommendation 55.

Recommendation 59 advocates the development of national and international registers on adverse effects with the use of blood components.

Recommendation 62 advocates the definition of subgroups of patients requiring different approaches for transfusion therapy.

Recommendation 64 advocates regular training workshops.

Recommendation 66 advocates permanent personal identification which should not be variable between hospital visits.

## Group 4 Rapporteur: C. Politis

No changes were made in the recommendations.

**The group decided, however, that the following list of items needed further exploration in the future.**

- Transfusion therapy should be regularly reviewed, and revised according to evidence
- There is an urgent need to define relevant clinical outcomes from transfusion, such as QOL and functional status
- Outcomes need to be defined and benchmarked for disease/condition specific groups, but also relevant demographic groups within populations (e.g. elderly, IHD)
- Outcomes need to be measured at relevant time points, including short and long-term
- Transfusion specific tools to measure clinical outcomes need to be developed and validated
- Consequences of withholding or giving transfusion need to be measured in relevant patient groups
- A better understanding of the optimal correction of anaemia and the optimum duration of correction is needed, for major patient groups, eg major surgery; chronic anaemia.
- Observational studies are needed to focus prospective studies on the outcome of transfusion therapy
- Large adequately powered randomised clinical trials in transfusion medicine are needed to optimise blood use
- Evaluate zero-risk versus risk-based analysis for overall decision making process for assessing safety and effectiveness of blood transfusion and cellular therapies
- Data from haemovigilance programmes should be used for learning and improvement
- When evaluating plasma derived products for treating coagulation disorders, the issue of alternative strategies and their clinical relevance should be taken into consideration. This is true for clinical outcomes as well as for cost-effectiveness issues
- The effectiveness and safety of plasma derived and recombinant products for treating coagulation disorders needs to be assessed.This is relevant in view of the different costs of treatments with plasma derived products as compared to recombinant products

- Research funding should be committed to generate adequately powered in clinical trials.
- Translation of high quality study findings in transfusion medicine, particularly related to RBC, are likely to be cost-saving
- Clinicians should receive training that enables design of and participation in clinical trials
- Registries should be established that include high quality relevant outcome data. These should be used to promote clinical trial that maximise patient and societal outcome
- Research is urgently needed to define optimum practice in management of massive bleeding including the optimum product(s)
- Need to evaluate clinical and cost effectiveness of new methods of monitoring haemostasis
- Clear SPCs of the different types of plasma intended for transfusion should be defined based on comparative studies
- The goals of plasma and platelets transfusion in non-bleeding patients need to be better defined in terms of clinical outcome
- Established and new transfusion therapies should be subject to Health Technology Assessment (HTA) taking into account :
    - Specific product characteristics
    - Specific patient groups
- As precautionary measures may have a major impact on health care resources. They require reassessement using HTA
- Developing common models for cost-effectiveness and cost benefit analysis in transfusion with a view to benchmarking would help in assessing and comparing action plan in transfusion medicine

# Recommendations

**Group 1** **Rapporteur: E. Seifried**

# 3. RECOMMENDATIONS

## 3.0. GENERAL

1) (New) Blood establishments across Europe must undertake all efforts to increase public awareness about future shortages in blood supply with respect to demographic changes. Measure shall be undertaken to increase the percentage of donations per capita on a regional basis.

2) (New) Measures have to be undertaken across Europe to be able to respond quickly to emerging pathogens and epidemic outbreaks of infections. Blood establishments across Europe shall be included into existing rapid alert systems for infectious diseases. The relevance of the infectious agents for the blood transfusion chain should be evaluated by the responsible authorities and necessary measures have to be balanced with the safety of the blood supply and communicated to the blood establishment. Each European country and each blood establishment should have a disaster plan in place.

3) (New) Evidence-based clinical guidelines shall be established across Europe in order to support best clinical practice in transfusion medicine.

4) (New) A European benchmark project should be undertaken and based on the results centres of excellence should be identified.

5) (New) Attention should be given to the development of effective education programmes in transfusion medicine at undergraduate and postgraduate level. A common curriculum should be agreed on and implemented.

6) (New) Develop long term donor and recipient biorepositories complying with biobanking best practices.

## 3.1. RED BLOOD CELLS

### 3.1.1. General

7) * (97) Reduction of inappropriate Red Cell use should help to minimise the incidence and severity of blood shortages. Hospital inventory management should be optimised and should include the use of blood ordering schedules and patient blood management.

8) (98) A blood exchange programme could be envisaged as a single office serving as a central co-ordinating base matching shortages and available stock in different blood centres. Such networks exist with varying success in several European centres. A pilot project would be necessary to assess whether the system would be useful or effective.

### 3.1.2. Residual risk

9) * (99) Introduction of new strategies to improve transfusion safety should be prioritised on the basis of achievable safety gains. Optimising blood transfusion practices in the hospital could be the most important goal in terms of health gain and cost benefit.

10) * (100) The administrative practices related to transfusion, including recipient identification and compatibility testing, vary widely across Europe. ABO mismatch remains a very serious problem. Effective systems that reduce this administrative risk must be identified and adopted particularly at the hospital level.

11) * (101) Based on clinical and organisational experiences pre-storage universal leucodepletion is highly recommended.

### 3.1.3. Product quality and clinical outcome

12) * (102) Optimum storage time and conditions as defined by patient outcome must be determined in prospective clinical trials.

### 3.1.4. Appropriate use

13) (103) Every hospital undertaking blood transfusion must have a quality management system in place, that includes a designated and specially trained professional with responsibility for the quality of transfusion practice in the hospital and that includes a systematic programme of ongoing education and a documented and systematic approach to clinical audit. This system of clinical audit should use accepted specified audit measures uniformly adopted across Europe and a standardised, published audit report format, with published annual reports.

14) * (104) Appropriate patient management programmes for transfusion should be established in every hospital.

*(105) [Attention should be given to the development of effective education programmes in transfusion at undergraduate and postgraduate level.]*
*deleted*

15) * (106) There is an urgent need for well-designed large-scale studies in blood transfusion in well-defined patient groups, addressing clinical safety and efficacy. Prospective randomized trials must be organised and funded from out-side the blood establishments.

16) (New) Blood establishments should analyse patterns of Red Cell use to provide an appropriate inventory for optimal patients care and to minimise Red Cell wastage. The effects of Red Cell transfusions shall be monitored on an individual basis so as to match the number of units transfused with the patient's need. In some circumstances one-unit Red Cell transfusion might represent optimal care.3.2. PLATELETS

### 3.2.1. Products and their availability

17) * (107) Platelet products should be prepared and stored in a fashion that retains adequate haemostatic function while maintaining the safety of the component.

18) * (108) Concerning availability, there is an urgent need to evaluate the impact of possible delays throughout the platelet transfusion chain resulting from new technologies or other safety measures. Blood services should be organised in such a way so as to:

- minimise temporary and other possible shortages, e.g. rare phenotype platelets; and

- minimise the wastage of products without compromising the quality and supply of platelet concentrates.

19) *109) [The implementation of NAT tests should enable the release of platelet concentrates preferably in less than 24 hours after donation]*
*(deleted)*

20) (New) The use of platelet-additive solutions in order to save plasma and to reduce side-effects of platelet transfusion is recommended where clinical equivalence of the novel platelet product is shown.

21) (New) Novel platelet-derived products for local treatment shall be established only after proper clinical evaluation and shall meet the same safety and quality requirements as blood products.

### 3.2.2. Indications and platelet transfusion threshold levels

22) (110) The clinical decision to transfuse platelets should be based on careful evaluation of the individual patient's condition, including bleeding history, bleeding tendency, in addition to actual platelet count or any laboratory result reflecting platelet function.

23) * (111) To support clinical decision making, it is strongly recommended that an algorithm for defining transfusion needs be developed. Such algorithms should be developed and implemented through the cooperative efforts of clinical and transfusion medicine specialists, and be subject to regular review. There is a need for rapid platelet function tests in selected patients at risk. Before implementation the clinical benefit has to be shown.

24) (New) There is an ongoing debate regarding the need for prophylactic transfusion of platelet concentrates in the treatment of thrombocytopenic patients. However the current standard of care is prophylactic treatment.

### 3.2.3. Dosage and efficacy

25) * (112) The outcome of platelet transfusion in terms of corrected count increment (CCI), for example, should be evaluated as a basis for improved transfusion practice. This involves assessing platelet recovery, actual increase in platelet count, and time (days) between two transfusions and most importantly clinical bleeding.

26) * (113) Research on developing better techniques to monitor the efficacy of platelet transfusion shall be supported.

### 3.2.4. Alloimmunisation and Refractoriness

27) * (114) Leucocyte depleted cellular blood components shall be used in all patients to prevent alloimmunisation. HLA- and/or HPA-compatible or cross-match negative platelets should be given to refractory alloimmunized recipients.

28) (New) Blood establishments across Europe should have the capability of diagnosing and managing the blood supply in autoimmune and neonatal thrombocytopenia.

### 3.2.5. Quality aspects and haemovigilance

29) *(115) [Development of algorithms in the appropriate use of platelet concentrates, in addition to the establishment of haemovigilance systems, is advocated as part of a quality system. The efficacy of platelet transfusion as well as the associated side effects should be assessed. Parameters on transfusion out-come should be registered and evaluated within an appropriate healthcare quality system.]*
*(deleted)*

30) (New) Measures shall be taken to reduce the risk of bacterial contamination in platelet concentrates. Different methods, such as testing and pathogen inactivation should be further investigated.

31) (New) The impact of ABO-incompatible platelet transfusion has to be clarified.

## FRESH FROZEN PLASMA

32) * (116) For improved safety, plasma for clinical use products that have been quarantined or pathogen attenuated should be used.

33) * (117) The clinical and biological results of Fresh Frozen Plasma for clinical use infusion should be monitored since there are different FFP preparations with different product characteristics available and the individual response of the patients with coagulation disorders may be variable.

34) * (118) Since the intended benefit of FFP is the correction of bleeding in patients with coagulation disorders, tests (which might include point of care) that assess the haemostatic functions and provide results rapidly are essential for its optimal use. This implies the permanent availability of a laboratory to perform coagulation tests.

35) (119) The dosage and duration of therapy should be determined by clinical evaluation * and serial determination of coagulation tests.

36) (120) The numerous existing guidelines should be harmonised. Their dissemination and implementation should be strongly reinforced by quality assurance systems. As a possible way to improved application, summarised guidelines should be included on prescription forms and their impact should be measured

37) (121) The education of health professionals should be improved.

38) (New) As a precautionary measures to reduce the risk of immune TRALI, in case of single donor plasma units it is recommended to use only male donors and females without a history of pregnancy. Alternatively adequate testing should be performed.

### 3.4. ALBUMIN

39) (122) The existing evidence from published clinical studies addressing albumin use for volume substitution is insufficient. A convincing elaboration of benefits of albumin with respect to measurable clinical endpoints in comparison to other colloids will need substantially augmented evidence by further well-designed clinical studies.

40) *[123 - Since a potential deleterious effect of albumin infusion has been highlighted in the Cochrane Injuries Group Albumin Reviewers meta-analysis, further studies on mortality are required.]*
*(deleted)*

41) (124) The impact of preparations with different albumin concentrations and their respective sodium content is unresolved and should be studied further with respect to clinical efficacy and economic consequences.

* *Modified*

**Group 2** **Rapporteur: P. Giangrande**

## Recommendations on clotting factor concentrates:

* (125) Registers of patients with haemophilia and related disorders should be established and maintained in each country.

* (126) Gathering pharmacovigilance information on such complications as inhibitor development, allergic reactions, viral transmission and other miscellaneous adverse events is mandatory. A European initiative (EUHASS) has recently been launched and it is hoped that this will be financed beyond the initial three year term.

* (127) A network of Comprehensive Care Centres should be established in each country and should provide a seven days a week 24 hour clinical and laboratory service and be accessible to all patients. In order to be so designated, such a centre should normally provide treatment for at least 40 patients with severe haemophilia in order to maintain the expertise required

* (128) Adequate amounts of coagulation factor concentrates for the treatment of patients with hemophilia and related disorders should be available in each country. There is a continuing need for both plasma-derived and recombinant products. At national level, the minimum acceptable level of factor concentrate use should be 2 units per capita. Coagulation factor concentrates are now included in the WHO list of essential medications and cryoprecipitate should no longer be used for the treatment of haemophilia

(New) In order to foster the cooperation of patient organizations and physicians, it is recommended that a formal mechanism be established in each country to develop best practice in haemophilia care.

* (130) The various guidelines from medical bodies in different countries should be harmonized and expanded to include advice on dosages for the treatment of common bleeding problems. These should include details of the level of evidence and grade of recommendations.

* (131) As a general rule, prophylactic treatment for children with severe haemophilia is recommended. Ongoing prophylaxis in adults may also be considered.

(New) Home treatment with coagulation factor concentrate should be encouraged in patients with severe haemophilia.

(132) Immune tolerance should be offered to all patients with haemophilia who develop clinically-significant inhibitory antibodies.

* (133) Data on outcome of treatment should be collected, including clinical data such as frequency of bleedings and assessment of joint function as well as quality of life and economic information.

(New) Family trees for patients with haemophilia and other inherited bleeding disorders should be drawn up and genetic counselling offered.

(New) Awareness should be drawn to rarer bleeding disorders which affect both men and women. Data on these patients should also be included in the national registers.

(New) Patients with rare bleeding disorders should be treated with specific coagulation factor concentrates wherever possible. The development of “orphan drugs” for the treatment of such patients should be encouraged. If fresh frozen plasma is used, it should be subjected to viral inactivation/removal treatment. Prophylaxis in patients with a severe phenotype should be considered.

(New) The European Union should foster the development of equitable care in all member states.

* *Modified*

**Group 3** **Rapporteur: W. Korte**

**Discussionpoints :**

## Transfusion : Qualitymanagement --- Clinical Management

134. There is an urgent need to foster the commitment of decision makers, both at national and local levels, to establish a Quality Management System within hospitals for the clinical use of blood products.

(New A) The implementation of a "Clinical Champion" (CC) status is suggested *(see also 136)*; CCs are persons with a recognizable track record for and first-hand clinical experience with the use of blood components.
CC activities should include educational activities *(see 138)*; "translation" and coordination between persons involved in the (centralized) process of production and the (decentralized) process of clinical use; to develop markers of efficacy and outcome; to develop or define potential surrogate markers for efficacy and outcome; to define minimal requirements for all aspects of blood component use (collaboration with national committee); to prospectively secure adherence to guidelines *(see 140)*; to look for and comment on under- or overuse of blood components *(see 137)*.

(New B) The realization of the transfusion quality management scheme is in the responsibility of the hospital management. It should be implemented in collaboration with the respective national committee where necessary. *(see 135)*

135. There is the need to ensure that a quality manager for clinical use of blood products is appointed and empowered to take appropriate actions to ensure and improve quality, in co-operation with the hospital transfusion committee; and the quality manager, along with the transfusion committee, should be responsible for defining and disseminating guidelines and SOPs for optimal use of blood products, and verifying their application by the healthcare professionals. *[to be modified for overlapping responisbilities with "new, A" and "new, B"]*

(New C) The quality management (QM) of blood component use needs to be integrated within the "total quality management" and "general risk assessment" of the respective institution e.g. hospital. Such a quality management system (QMS) needs to allow incorporation of all aspects of the production chain. It must be simple and must be applicable everywhere. It needs to recognize outcome as a parameter that is to be monitored. It incorporate hemovigilance tools. *(see 135)*

(New D) National legislation / regulations need to be modified (where necessary) to allow development of tasks mentioned in "new B".

(New E) The development and/or support of a national and international register on adverse events with the use of blood components is to be targeted. This should be supported by "Clinical Champions". *(see new, A)*

136. There is the need to ensure that strategies are developed to maximise the cooperation of all healthcare professionals in the achievement of optimal use of blood products *(see new, A)*.

137. There is an urgent need to carry out controlled studies to define the appropriate use for blood products and the parameters needed to evaluate their effcacy and outcome; to document the indications for the use of blood products on the request form; and to define a limited number of common indicators in order to allow comparison between different hospitals and increase awareness of inappropriate use. *[to be modified for overlapping areas with "new, A" and "new, F"]*

(New, F) Subgroups of patients that will require different kinds of approaches for transfusion therapy need to be defined, e.g. patients that need therapy of acute bleeding; prophylaxis in the periinterventional setting; prophylaxis / therapy in oncology.
It is necessary to recognize the need to differentiate therapeutic approaches in different patient populations.

138. There is an urgent need to foster a continuing education programme for healthcare professionals involved in the clinical use of blood products organised by the transfusion committee; and the inclusion of transfusion medicine in undergraduate and postgraduate training. *(see new, G)*

(New, G) Regular training workshops (both for new and experienced users) should be offered on a national and/or regional level. Workshops with experienced users should be utilized to develop and improve the training procedures and to develop new or improve existing standards (e.g. within working groups). These processes should occur in collaboration with the national committee.

139. In defining SOPs, particular attention should be given to preventing transfusion errors, re-engineering the process, and introducing, if possible, information instruments, such as portable barcode readers, to assess the identity of the patient, the blood samples and the assigned unit.

(New, H) Person identification ("traceability") should be permanent (e.g. not variable for different hospitalizations); every potential possibility to reduce and prevent transmission errors must be taken hold of; these issues need to be considered at any point during the process, i.e. beginning with the screening of the donor to the follow-up of the recipient.

140. The establishment of an integrated hospital information and documentation system is strongly recommended, since this could greatly facilitate the collection and analysis of data related to the use of blood products.

**Group 4** **Rapporteur: C. Politis**

# EFFICACY IN TERMS OF OUTCOME (INCLUDING ECONOMICAL ASPECTS)

## Conclusions and recommendations

### Recommendations of economic aspects (141 – 150) from Kreuth Initiative in 1999 are still valid.

#### Information needs

141 - The epidemiology of blood components and blood products use should be assessed in the European to determine the likely clinical need and assist in planning future provision

142 -Blood and blood products use for the treatment of patients with index conditions should be recorded for each country on an annual basis, to provide baselines and indicators for comparison

143 - Consideration should be made for a linkage between product usage and the clinical conditions for which they are being used. This might be best achieved through the use of automated databases, the use of electronic patient records and electronic prescribing

144 - Reviews of blood and blood products use should be conducted using economics as well as clinical measures to determine the patterns of usage, to ascertain appropriateness of use, and to assess the effect of education programmes. Indicators should be developed to reflect optimum usage

145 -Consideration should be given to sponsoring these kinds of studies across the EU and else where

#### Future demands

146 - It is recognised that there are changes underway in the relative use of the plasma derived albumin, immunoglobulins, Fs VIII and IX. This will have important consequences on the costs and availability of these products in the future.
A study of the future demand and need for blood and blood products should be undertaken with appropriate assessment of the economic factors to determine the viability of blood collection and fractionation centres

147 - Considerations should be given to the rational distribution of these centres throughout the EU, their commercial viability and national dependency in the context of self-sufficiency

**Educations requirements**

148 - Undergraduate and post-registration educational and training of all clinicians who use blood and blood products should be promoted. Ways of increasing the impact of clinical recommendations and guidelines should be investigated

**General recommendation**

149 - Economic evaluation should underpin the drive to improve the efficiency of resourcing and optimal use of blood and blood products, while maintaining the principle of voluntary non-remunerated donors

150 - The principle and the need for self-sufficiency should be re-assessed in the context of safety, availability, ethics and economics, in view of continuing development of the EU and other countries

**For new recommendations a comprehensive list of items needs further exploration in the future (look at page 322).**