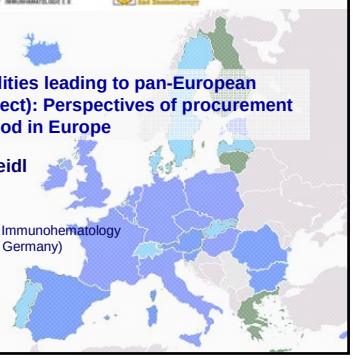
Joint Annual Congress of the DGTI and ESFH in cooperation with the SFTS
Düsseldorf, 16.-19. September 2008
Workshop: Seltene Blutgruppen



Differences and communalities leading to pan-European standards (The EuBIS Project): Perspectives of procurement and transfusion of rare blood in Europe

Prof. Dr. med. Christian Seidl

Institute of Transfusion Medicine and Immunohematology
Red Cross Blood Service (Frankfurt - Germany)

TREATY PROVISIONS

Article 152 - ***EU Treaty (Amsterdam 1997)***

Article 152 (4) (a) (ex Article 129, EU Treaty-Maastrich 1992)

4 ...**Shall contribute to the achievement of the objectives referred to in this Articles through adopting:**

(a) Measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives, these measures not prevent any member States from maintaining or introducing more stringent protective measures.

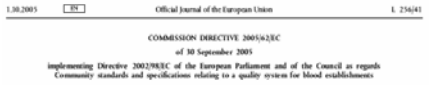
‚the European blood legislation requirements'

Directive 2002/98/EC and its **technical annexes**.

Directive 2004/33/EC – Tech. Requirements

Directive 2005/61/EC – Traceability and SAR / SAE

Directive 2005/62/EC Quality Management



1.10.2005 EN Official Journal of the European Union L 256/41

COMMISSION DIRECTIVE 2005/62/EC
of 30 September 2005
implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments

Article.2: … the Commission shall take fully into account the detailed principles and guidelines of **Good manufacturing practice (GMP)**, as referred to in Article 47 of **Directive 2001/83/EC**.

EU-TREATY PROVISIONS

Substances of human origin: the legal basis for EU law

- Article 152: public health
  - Objective: health protection ⇒ minimum standards
  - Example: Blood Directive 2002/98/EC
    Tissue Directive 2004/23/EC
- Article 95: internal market
  - Objective: free circulation ⇒ harmonisation
  - Example: Medicinal Products Directive 2001/83/EC

with kind permission from Th. Bregeon, European Commission 2008 (modified)

‚The European Commission'

supporting the implementation of the blood legislation

TOGETHER SINCE 1957

PROJECTS FUNDED IN 2003-2006

Blood

- Standard operating procedures for collection and processing (2004)
- Standards for inspections (2006)
- Optimal use (2006)
- **Optimal Donor Management (2007)**

EU-Q-Blood-SOP
Methodology for standard operational procedures
Co-funded by the EC (2A2004217

EuBIS
European Blood Inspection System

Optimal Blood Use Project

DOMAINE

with kind permission from Th. Bregeon, European Commission 2008

Public Health & Risk Assessment, Directorate General, DG SANCO

EU-Q-Blood-SOP Project

Project objectives

Develop a Manual describing a methodology based on good practice that will

(1) **assist blood establishments to implement or expand their standard operating procedures (SOPs).**

(2) contribute to the understanding and management of quality processes in blood services.

(3) **assist blood establishments in preparing for the inspection of their services** related to the implementation of quality relevant elements required by the EU directive 2002/98/EC.

EU-Q-Blood-SOP
Methodology for standard operational procedures
Co-funded by the EC QA2004217

EU-Q-Blood-SOP Manual

Translations:

English
German
French
Spanish
Czech
Polish
Hungarian
Bulgarian
Russian

http://www.eubis-europe.eu

EuBIS
European Blood Inspection System

EuBIS - General Objectives

(1) define requirements for quality management systems of blood establishments based on the Directive 2005/62/EC.

(2) develop pan European standards and criteria for the inspection of blood establishments based on GMP guidelines to assist national inspections in implementing the Directive 2002/98/EC and its technical annexes.

(3) establish a common benchmark system for continual improvement. This benchmark system should develop practical assistance and advice to optimise processes based on good practice among blood establishments.

(4) develop a training programme for inspectors

EuBIS
European Blood Inspection System

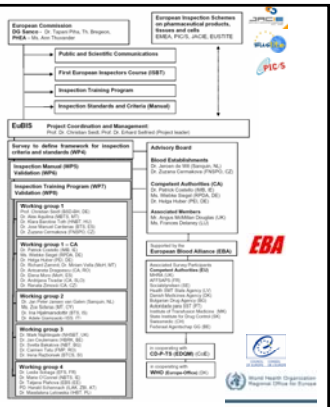
Project Structure

European Commission – Directorate C
Dr. Tapani Piha (DG Sanco)
Mr. Thomas Bregeon (DG Sanco)
Ms. Ann Thuvander (PHEA)

Project Coordination (DE):
Prof. Dr. C. Seidl and
Prof. Dr. E. Seifried (Leader)

Participants from 20 EU Member / EFTA states:

AT, DE, MT, HU, CZ, NL, CY, IT, UK, BE, BG, RO, FR, ES, EE, IE, PL, LU, SLO, IS



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate C - Public Health and Risk Assessment
C6 - Health measures

Meeting of the Competent Authorities on blood and blood components (Art. 25 Dir. 2002/98/EC)

18 October 2007

7. Presentation of projects under the public health programme in relation to blood and blood components

7.1 Outcome of the EU-Q-BLOOD SOP Project (European standard operating procedure (SOP) methodology reflecting European best practice

7.2 Presentation of the EUBIS Project (pan-European standards and criteria for the inspection of blood establishments)

Evaluation Code: EuBIS-Survey-XX-XX

EuBIS
European Blood Inspection System - Project

Survey-Questionnaire

The **specific objectives of this survey** are

to define the current situation of standards and criteria used for inspections of blood establishment among the participants from 17 established, new, applicant and EFTA states in order to identify

- (A) international and national inspection guidelines in place and
- (B) the current inspection practice.

Inspection and QS - Survey

20 competent authorities
17 blood establishments and governmental institutions

27 EU member /EFTA-EEA states:

Supported by EC, DG-SANCO

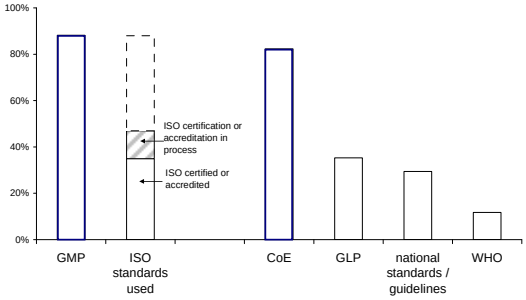
EuBIS Survey – Blood establishments activity profiles

Co-funded by the European Commission, DG Sanco

Activity	%
Blood component preparation	
Cellular (Erythrocyte and / or Platelet concentrates	100
Fresh Frozen Plasma (whole blood)	94
Apheresis component preparation	
Apheresis Erythrocyte / Platelet concentrates	100
Apheresis Fresh Frozen Plasma	75
Related preparations	
Stem cells	75
Cord blood	31
Granulocytes	69
Lymphocytes	50
Source Plasma for Fractionation	75
Cryoprecipitate	56
Autologous blood components	88

Seidl et al,Vox Sanguinis, 2008

Section I - Common standards used for quality systems of blood establishments



EuBIS Inspection manual

Eu Directives } Legislation

Common Standards

EU-GMP
PIC/S for BE
CoE guide
ISO
} Inspection standards

Common Criteria

Defining the inspection process
Organisational requirements
Evaluation system for deviations
} Linked to EMEA / PIC/S EUSTITE / JACIE

EuBIS Inspection Manual

Chapter 1: Quality system (standards-cross reference)

Chapter 2: Organisational requirements of a CA / BE
- Qualification and training of inspectors
- Inspection Master Plan (Schedule)
- Number of inspectors (staff) to cover the task

Chapter 3: Inspection process of BE (external by CA)
- Type of inspection
- Inspection team
- Information provided by the BE to CA before inspection
- Documents/Lists of SOP (optional)
- Information available on site during the inspection by CA
- Inspection report
- Evaluation system for deviations

Chapter 4: Self-Inspection process (internal by BE)
- Quality policy (Management)
- Type of inspections
- Responsiabilities
- Inspection team (e.g Peer-inspection process)
- Internal inspection report
- Evaluation system for deviations and continuous improvements

Chapter 5: Inspection checklists

Member Consultation:
Movement of labile blood products

EBA European Blood Alliance

As of**: August/September 2007**

Questionnaire:

1. Do you have a legal system regulating the **self-sufficiency in labile blood products** in your country? Yes / No

2. If there is a legal basis please could you send a copy of the corresponding laws; please indicate when this law was installed.

3. If there is no legal basis please let us know whether or not **your government allows the importation of labile blood products.**
Yes it allows importation / No it does not allow importation

Country:	Question 1: (Do you have a legal system regulating the self-sufficiency in labile blood products in your country. Yes or no?)	Question 2: (If there is no legal basis please let us know whether or not your government allows the importation of labile blood products. Yes it allows importation/no it doesn't allow importation)
Belgium, Flanders	Yes	N/A
Belgium, Wallonia	No	Yes, (by health authorities in special circumstances for some needs and exchange near the Belgian border (not much))
Denmark	Yes	No
England & N. Wales	Yes (labile blood; donated blood and the components that are derived from it, such as platelet concentrates)	Yes (within the limits of the EU directive(s))
Estonia	No	Yes
Finland	Yes (labile blood products from EU countries that meet the requirements of the Directive)	Yes
France	Yes	Yes (restricted)
Germany, GRC	No	Yes
Latvia	Yes	No
Lithuania	No	Yes
Luxembourg	Yes	Unknown
Malta	See appendix	See appendix
Netherlands, the	Yes	Yes
Norway	No	Yes
Portugal	Yes	Yes (only under a Government request)
Slovenia	Yes	Yes
Sweden	No	Yes
Switzerland	No	Yes (importation is restricted to special situations. One exception is Octaplas which is from Swedish donors and produced in Vienna. Red cells only for rare blood groups (from Amsterdam).
Wales	No	Yes (one Marrow/PBSC and rare RBC phenotypes are currently imported as required)

EBA European Blood Alliance

SEE Blood safety project

World Health Organization Regional Office for Europe

The project comprises two components.

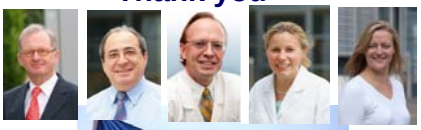
Component one (focused on the harmonization of national blood safety policies/ strategies, to ensure the basis for further technical developments)
Strengthening mutual trust and acceptability of the quality of blood in the region
Objectives:
a) The development of national policies on blood safety in accordance with EU directives and international recommendations in the fi eld.
b) Increasing the availability of blood and blood components through sustainable promotion of voluntary non-remunerated blood donations.

Component two (focused on some specific technical issues)
Increasing trans-national availability of safe blood for medical emergencies and special circumstances, as well as availability of rare blood group donations
Objectives:
a) Building a regional network of institutions and professionals able to respond to both national and regional needs.
b) Establishing a regional information system (E-network) for a rapid identification of blood availability.
c) Setting up mechanisms for rapid transportation of blood and blood components.

Albania
Bosnia and Herzegovina
Bulgaria
Croatia
Republic of Moldova
Romania
Serbia
Montenegro
The former Yugoslav Republic of Macedonia

www.eubis-europe.eu

Thank you



http://www.eu-q-blood-sop.de

http://www-eubis-europe.eu