

Implications of the EU Blood Directive on Hospital Blood Banks

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Aim of the Directive

To ensure that blood and its components are of comparable quality and safety throughout the transfusion chain in all Member States.

Setting *minimum* Community Standards

Directive 2002/98/EC of the European Parliament and of the Council

Setting standards of quality and safety
for the collection, processing, storage
and distribution of human blood and
blood components and amending
Directive 2001/83/EC

Commission Directive 2004/33/EC

Implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components.

The Directive must be transposed into Irish Law by 8th February 2005

This will be LAW
not a guideline

There will be provision
for a 9-month
concession to enable
Member States to
become compliant
under the new
legislation



Definition of a Blood Establishment

“Any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage and distribution when intended for transfusion”.

Definition of a Hospital Blood Bank

“A hospital unit which stores and distributes and may perform compatibility tests on blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities”.

Only some of the Articles of the Directive apply to Hospital Blood Banks

- Hospital blood banks have a limited number of activities (compared to blood establishments)
- Concensus had to be found between Member States
- Accreditation or licencing procedure does not apply to hospital blood banks

Directive 2002/98/EC

The following Articles apply to Hospital Blood Banks

Article 10	Personnel
Article 11	Quality System
Article 12	Documentation
Article 14	Traceability
Article 15	Notification of Serious Adverse reactions and events
Article 22	Storage, Transport and Distribution
Article 24	Data Protection and Confidentiality

Article 10 Personnel

-shall be qualified
-and be provided with timely, relevant and regularly updated *training*

Training Issues

- Facilities
- Cost (staff time)
- Training Officer (appropriately qualified)
- Number of On-Call Staff
- Level of training is not defined



Article 11 Quality System

“Establish and maintain a quality system based on principles of good practice”.

The technical requirements for the standards relating to a specific quality system have not yet been finalised

A Quality System would include:

- Quality Policy, Management System and Objectives
- Personnel Responsibilities
- Premises and Environment
- Equipment, Information Systems and Reagents
- Examination Processes
- Quality Control, Evaluation and Quality Assurance
- Quality Improvement

Article 12

Documentation

“Member States shall take all necessary measures.....to maintain documentation on operating procedures, guidelines, training and reference manuals, and reporting forms.”

Documentation....



- Any laboratory with CPA Accreditation (or that is preparing for CPA Accreditation) should be in a position to comply with the documentation requirements.
- Document Control is an on-going process.

Article 14 Traceability

“Member States shall....ensure that blood and blood components collected, tested, processed, stored, released and / or distributed on their territory can be traced from donor to recipient and vice versa.”

Traceability Issues



- Further clarification and expert opinion are still required at EU level to reach agreement on Traceability.
- Possibly the biggest cost implication for Irish Hospital Blood Banks – if this article is fully addressed electronically.

Laboratory Information Systems

Provide positive confirmation that a particular product has been received by the hospital.

Can place an ultimate “fate” against a unit.

BUT - confirmation that transfusion has actually taken place relies mainly on manual systems – checking sign-out ledgers and looking in patient’s charts.

Electronic Traceability:

- Bar-Coded patient Wristbands
- Print sample ID at bedside
- In lab, bar-coded sample info is wanded into laboratory information system
- Crossmatch label includes barcoded patient information
- At bedside, crossmatch label cross-checked with patient wristband
- Confirmation that Transfusion has actually taken place
- Benefit of safer transfusion for patient

Article 15 Notification of Serious Adverse Events and Reactions

“Any serious adverse reactions observed during or after transfusion which may be attributed to the quality and safety of blood and blood components shall be notified to the competent authority.”

Notification Issues

- i.e. Mandatory (not Voluntary) Reporting
- Directive says: report to Competent Authority within 24 hours
- A Responsible Person must be nominated
- Reactions “attributed to the quality and safety of the product” – therefore different to what we term as “Transfusion Reactions”
- However, further clarification and expert opinion are also required before agreement is reached (at EU level) on the procedure for notification of adverse events and reactions

Article 21

Storage, Transport and Distribution Conditions

Storage

- Temperature and humidity in storage areas must be controlled, monitored and checked
- Alarm system
- Access restricted
- Environmental Monitoring conducted

Transport and Distribution

Packaging must be adequate to resist damage and maintain acceptable storage conditions during transportation.

Transport and distribution of blood and blood components at all stages of the transfusion chain must be under conditions that maintain the integrity of the product.

Transport Issues

- There is confusion with regard to the transporting of blood off-site
- Hospital blood banks that have a formal arrangement to transport blood to/from other hospitals may be classified as blood establishments....
- What happens if blood is transported with a patient to another hospital?
- In any case, a **validated** system is required to transport blood.
- Standardised system of (blood) transport desirable

Article 23 Data Protection and Confidentiality

Software must be validated

Users must be trained and appropriate levels of authorisation defined

Backup procedures must be in place in the event of failure

There must be provision for archiving

No unauthorised disclosure of information

Hospital Blood Banks that Irradiate or perform Pre-Deposit Autologous Donation

These hospitals by nature of the fact that they collect and/or process blood or blood components will be classed as Blood Establishments.

They must be inspected and will need a licence.

**Member States shall designate
the competent authority
responsible for implementing the
requirements of the Directive**

In Ireland, the Irish Medicines Board
(IMB) have been nominated as the
Competent Authority.

Since the Finlay Tribunal report in 1997,
the IMB have been inspecting the IBTS
twice yearly.

IMB

From 8th February 2005 , the IMB will be responsible for designation, authorisation, accreditation or licencing of blood establishments and for ensuring that hospital blood banks adhere to the articles of the Directive.

- The IMB must familiarise themselves with the activities of hospital blood banks
- Planned visits to small / medium / large hospital sites
- Although they have the authority, do they have the competence?
- (For CPA Accreditation, inspection is by peers)

What has been done so far?

- May 2004 – Workshop organised by the Blood Policy Division of the Dept. of Health and Children
- A Multi-Sectional Group has been formed – members include IMB, IBTS, Medical Scientists, Dept. of H+C and Hospital Management
- IBTS are assigning a team to do a gap analysis
- TSAB are assessing infrastructure (staffing and equipment) in hospital laboratories

At hospital level, Chief Medical Scientists and their consultants have made submissions to hospital management for extra staff – e.g.

Quality Officer

Senior post with responsibility for training

Transfusion surveillance officer

Impact of the Directive

This will depend on the current status of the blood transfusion service in each Member State - and the degree of implementation that the Member States and their Competent Authority pursue.

Inevitably there will be differences in these efforts and the degree of compliance will vary.

Member States may exceed the Directive Standards.

Impact of the Directive

At European level, the greatest impact of the EU Blood directive will be on the newer Member States.

At Irish Hospital Blood Bank level, the issues of training, transporting blood between hospitals, nomination of a responsible person, establishing a quality system and introducing full electronic traceability still need to be addressed.