THE EU DIRECTIVE AND HAEMOVIGILANCE

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SHOT 6th July 2004
Purpose of the Directive

“To ensure that blood and its components are of comparable quality and safety throughout the blood transfusion chain in all Member States, bearing in mind the freedom of movement of citizens within Community territory.”
“Mother Directive” 2002/98/EC

Setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components

Becomes Law in Member States 8/2/05

- Text agreed October 2003
- Implementing Directive 2002/98/EC as regards certain technical requirements for blood and blood components
- Published in OJEC March 2004
- To become part of the Law 8/2/05
Second “Daughter” Directive

1st draft out for consultation - November 2003
2nd draft - EU website 25 May 2004
Consultation period ends 15 July 2004

Setting technical requirements for Quality Management systems, traceability requirements and notification of serious adverse reactions and events

Should become part of the Law 8/2/05
Directive 2002/98/EC

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Recitals - inform and add depth to the articles
Recital 12

Hospital blood banks are hospital units which perform a limited number of activities, storage, distribution and compatibility tests ... only provisions relevant to these activities should apply to hospital blood banks

Article 3 - Definitions

‘Hospital blood bank’ shall mean 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
Article 6

Denotes the articles that shall apply to hospital blood banks, which are:

7 Provision for existing establishments
10 Personnel
11(1) Quality system
12(1) Documentation
14 Traceability
15 Notification of serious adverse events and reactions
22 Storage, transport and distribution conditions
24 Data Protection and confidentiality
Article 7
Provisions for Existing Establishments

Provision for 9 months concession after February 2005 to enable Member States to become compliant under this new legislation

i.e. Period of 9 months grace
Article 11(1) - Quality System

Member States shall take all necessary measures to ensure that each blood establishment (and hospital blood bank) establishes and maintains a quality system based on the principles of good practice.
Article 12(1) - Documentation

... take all necessary measures in order to ensure that blood establishments (and hospital blood banks) maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms.
Quality Management System

Draft “Daughter” Directive

Currently includes:-

- Personnel and organisation
- Facilities / premises
- Equipment and materials
- Procedures
- Release of products
- Storage and despatch
- Contract management
- Deviations, complaints, recall, errors and accidents (haemovigilance)
Article 14 - Traceability (‘Mother’) 

... take all necessary measures in order to ensure that blood and blood components collected, tested, processed, stored, released and/or distributed can be traced from donor to recipient and vice versa.

Draft Daughter Directive

Traceability - the ability to track each individual blood unit or blood component derived thereof to the transfused recipient(s) and back to a potentially implicated donor.
Recital 17 - Traceability - “Mother”

An adequate system to ensure traceability of whole blood and blood components should be established. Traceability should be enforced through accurate donor, patient and laboratory identification procedures, through record maintenance, and through appropriate identification and labelling system.
Article 14 - Traceability - “Mother”

• Data needed for full traceability shall be kept for at least 30 years

• Draft Daughter - QMS Documentation: ALL RECORDS, including RAW DATA which are critical to the safety and quality of the blood and blood components, should be kept in a secured storage area for 30 years.
Traceability. How well do we do at present?

HCV Lookback, 1995

- 399 components
- 68 (17%) not traced

- 37 no record in hospital BB
- 22 insuff patient details to find in hospital records
- 6 BB records OK, no traceable hospital records
- 3 "other"

Dike et al, Transf Med, 1998, 87-95

Lookback on 160 components. 14 untraceable. “Transfusion records were rarely complete in the patients' case notes and data were largely collected from manual and computerised blood bank records.”


Slide courtesy of M Bruce, BBTS EU Directive Meeting 09/06/04
Article 15 - Notification of Serious Adverse Events and Reactions

Any serious adverse events (accidents and errors) related to the collection, testing, processing, storage and distribution of blood and blood components which may have an influence on their quality and safety, as well as any serious adverse reactions observed during or after transfusion which may be attributed to the quality and the safety of blood and blood components are to be notified to the competent authority.

Notification format - Daughter Directive out for consultation.
EU Directive and Haemovigilance

Seems to imply that haemovigilance is confined to those events that are related to the quality and safety of components provided by blood establishments and does not include the errors made within the hospital framework.
Recital 18 - Haemovigilance System

To this end a common system of notification of serious adverse events and reactions linked to collection, processing, testing, storage and distribution of blood and blood components should be established in Member States.
Article 3 - Definitions

(g) ‘Serious adverse event’ shall mean any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood and blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients, or which results in, or prolongs, hospitalisation or morbidity
Article 3 - Definitions

(h) ‘Serious adverse reaction’ shall mean an unintended response in donor or in patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity.
Article 3 - Definitions

(l) ‘Haemovigilance’ shall mean a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow up of donors.
Draft Daughter Directive

Member states should have:-
• Procedures to record serious adverse reaction(s) related to the quality and safety of blood and blood components in both blood establishments and in institutions where blood is transfused would be required.

Ensure that:-
• Procedures are in place both in blood establishments and in institutions where blood is transfused to record any serious adverse event(s) related to the quality and safety of blood and blood components
18. The competent authority would need to be notified expeditiously (within 24 hours) of such adverse reactions, in case there was a possible transmission of infectious agents *that may cause* an adverse reaction in patients, as well as the actions taken with respect to other implicated and distributed components.

19. The competent authority also would need to be notified expeditiously (within 24 hours) by blood establishments, or institutions where blood is transfused, of serious adverse reactions observed in patients during or after transfusion *that may be* attributed to the quality and safety of blood and blood components.
# Draft Daughter Directive

## ANNEX IIIA

<table>
<thead>
<tr>
<th>Causality scale</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Excluded</td>
</tr>
<tr>
<td>0</td>
<td>Unlikely</td>
</tr>
<tr>
<td>0</td>
<td>Not assessable</td>
</tr>
<tr>
<td>1</td>
<td>Possible</td>
</tr>
<tr>
<td>2</td>
<td>Likely, probable</td>
</tr>
<tr>
<td>3</td>
<td>Certain</td>
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</tbody>
</table>
# EU Blood Directive

## Draft Daughter Directive

### ANNEX IIIB - ‘expeditious’ notification format

<table>
<thead>
<tr>
<th>Type of Serious Adverse Reaction</th>
<th>Causality Scale</th>
<th>Clinical Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunological Haemolysis</td>
<td><em>Due to ABO incompatibility</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Due to allo-antibody</em></td>
<td></td>
</tr>
<tr>
<td>Non-Immunological Haemolysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-Transfusion Bacterial Infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anaphylaxis/Hypersensitivity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TRALI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-Transfusion Viral Infection</td>
<td><em>HBV</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>HCV</em></td>
<td></td>
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<tr>
<td></td>
<td><em>HIV</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Other</em></td>
<td></td>
</tr>
<tr>
<td>Post-Transfusion Parasitical Infection</td>
<td><em>Malaria</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Other</em></td>
<td></td>
</tr>
<tr>
<td>Post-Transfusion Purpura</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GVH Disease</td>
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</tbody>
</table>
but

4. The competent authority shall organise inspection and other control measures as appropriate in the event of any serious adverse event or reaction or suspicion thereof, in accordance with Article 15 notification of serious adverse events and reactions, which does apply to hospital blood banks.
Take Home Messages

EU Directive - Not just to regulate the Blood Services

8 of the 34 articles - Directly applicable to hospital blood banks

This is Law, not “Guidance”

UK Government *must* designate a competent authority to regulate Blood Establishments by February 2005, but must also indicate how it will demonstrate compliance by Hospital Blood Banks and for Haemovigilance
Take Home Messages

- Inspection and accreditation system
- Mandatory notification of serious adverse events/reactions followed by follow-up inspection and investigation
- Full Traceability of electronic hospital blood bank records
A brave new dawn