

THE EU DIRECTIVE AND HAEMOVIGILANCE

DR ANGELA ROBINSON
Medical Director, National Blood Service

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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

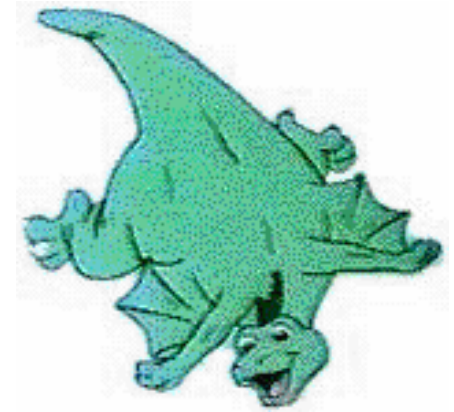
Setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components

Becomes Law in Member States 8/2/05



First “Daughter” Directive 2004/23/EC

- 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



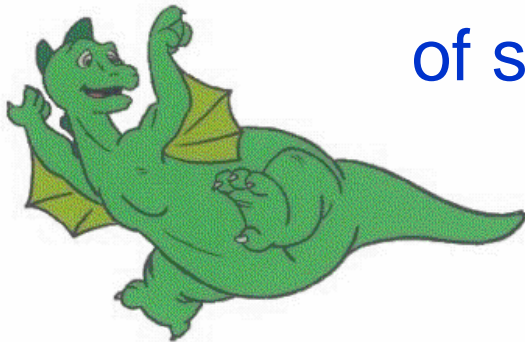
Second “Daughter” Directive

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

Recitals	33
Articles	34
Annexes	4

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

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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.

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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



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."

Pawson et al, Transf Med, 1999, 189 - 193

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

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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***

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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

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ANNEX IIIA

Causality scale		Explanation
0	Excluded	When there is conclusive evidence beyond reasonable doubts for attributing the adverse reaction to alternative causes
0	Unlikely	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components
0	Not assessable	When there is insufficient data for causality assessment
1	Possible	When the evidence is indeterminate for attributing adverse reaction to the blood or blood component or to alternative causes
2	Likely, probable	When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component
3	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component

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ANNEX IIIB - 'expeditious' notification format

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

Article 8 - Inspection and Control Measures (for Blood Establishments only)

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 → follow-up inspection and investigation
- **Full Traceability** → electronic hospital blood bank records



A brave new dawn