Safeguarding public health

Blood Safety and Quality Regulations

Thursday 29 September 2005
Hastings Stormont Hotel, Belfast
Current & Future Legislation - European Directives & UK Regulations

September/October 2005
European Legislation

Current
- Directive 2002/98/EC
- Directive 2004/33/EC

Future
- Technical Directives
  - haemovigilance/traceability
  - quality systems

United Kingdom Legislation

Current
- SI 2005/50 (Principal Regulations)
- SI 2005/1098 (Amending Regulations)

Future
- SI 2005/#### (November 2005 Amending Regulations)
- SI 2006/#### (Amending Regulations Implementing Technical Directives)
Current European Legislation:

  - setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC
    - Entry into force: 8 February 2003
    - Implementation deadline: 8 February 2005

  - implementing Directive 2002/98/EC…as regards certain technical requirements for blood and blood components
    - Entry into force: 11 April 2004
Current United Kingdom Legislation

- The Blood Safety and Quality Regulations 2005 No. 50 (SI 2005/50)
  - Coming (fully) into force: 8 November 2005

- The Blood Safety and Quality (Amendment) Regulations 2005 No. 1098 (SI 2005/1098)
  - Came into force: 8 April 2005
# Directive 2002/98/EC

## Applicability of Main Provisions

<table>
<thead>
<tr>
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<tbody>
<tr>
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<td>Provisions applicable to Hospital Blood Banks</td>
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<td>Provisions for existing establishments</td>
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<td>Inspection &amp; control measures</td>
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<td>11</td>
<td>Quality system requirement</td>
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<td>12</td>
<td>Documentation requirement</td>
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<td>Traceability</td>
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# Directive 2002/98/EC

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<tr>
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<td>16-19</td>
<td>Donor eligibility, examination and information</td>
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<td>20</td>
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<td>Quality &amp; safety requirements for blood &amp; blood components</td>
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<td>24</td>
<td>Data protection &amp; confidentiality</td>
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## Directive 2004/33/EC
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<td>Provision of information to prospective donors (Annex II)</td>
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<td>Autologous donations</td>
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<td>Validation (of testing &amp; processes referred to in Annexes II – V)</td>
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## The Blood Safety and Quality Regulations 2005 No. 50 (SI 2005/50)

<table>
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<td>2</td>
<td>Designation of the competent authority and scope of the Regulations</td>
<td>✓</td>
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<td>Suspension or revocation of authorisation</td>
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<td>The responsible person for a blood establishment</td>
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<td>Labelling of blood &amp; blood components and traceability</td>
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<td>Service of notices relating to hospital blood banks</td>
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<td>12</td>
<td>Objections to suspensions, revocations etc.</td>
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<td>Import of blood and blood components into the United Kingdom</td>
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<td>Disclosure of information by blood establishments &amp; hospital blood banks</td>
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<td>Powers of entry, etc</td>
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<td>18</td>
<td>Criminal offences</td>
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<td>Fees</td>
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<td>Consequential amendments</td>
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The Blood Safety and Quality Regulations 2005 No. 50 (SI 2005/50)

Schedule to the Regulations

- Part 1
  - Definitions

- Part 2
  - Information Requirements for Donors
    - Part A - Information to be provided to prospective donors
    - Part B - Information to be obtained from donors by blood establishments at every donation

- Part 3
  - Eligibility Criteria for Donors
    - 1. Acceptance criteria
    - 2. Deferral criteria

- Part 4
  - Storage, Transport & Distribution Conditions for Blood & Blood Components (including additional requirements for autologous donations)

- Part 5
  - Quality & Safety Requirements for Blood & Blood Components
### The Blood Safety and Quality (Amendment) Regulations 2005  No. 1098 (SI 2005/1098)

<table>
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<tr>
<td>1</td>
<td>Citation, commencement &amp; interpretation</td>
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<td>✓</td>
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<tr>
<td>2, 3, 4(a), 5, 6 &amp; 7</td>
<td>Amendments to Regulations 4, 5, 12, 16, 17 &amp; 18 of SI 2005/50 (making minor corrections)</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>4(b) &amp; 4(c)</td>
<td>Amendments to Regulation 12 of SI 2005/50 (concerning objections to notices served by the Sec. of State on blood establishments or hospital blood banks)</td>
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<td>✓</td>
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<td>Amendments to Regulation 19 of SI 2005/50 (concerning penalties for criminal offences and the maximum period of imprisonment on summary conviction)</td>
<td>✓</td>
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</table>
The Blood Safety and Quality (Amendment) (No. 2) Regulations 2005

- Currently the subject of a formal consultation by MHRA (MLX 327) to amend SI 2005/50.
- Consultation ends 30 September 2005.
- It is proposed that the Amending Regulations will come into force on 8 November 2005.
Proposed amendments to SI 2005/50:

- Provision of authority for fees to be charged on respect of:
  - Inspection of 3rd party testing laboratories.
  - Receipt and assessment of annual compliance reports from hospital blood banks.
  - Operation of a haemovigilance system for the receipt and assessment of serious adverse events and serious adverse reactions.

- Introduction of a provision to remove from a blood establishment authorisation a “Responsible Person” who has failed to carry out his responsibilities under SI 2005/50.
Proposed amendments to SI 2005/50 (continued):

- A change to the timing of when the periodic fee associated with a blood establishment authorisation becomes payable.
- A change in the timing for the initial and subsequent submission of blood bank compliance reports.
- Clarification that a hospital blood bank, in addition to operating as such, may seek authorisation as a blood establishment if it wishes to continue to collect or process blood or blood components.
- To extend the provision in SI 2005/50 concerning protection from incrimination of spouses to include civil partners.

- Adoption by European Commission in September 2005?
- 1 year to be allowed for transposition into national legislation?
- 12 Articles
- 3 Annexes

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<tr>
<td>2</td>
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<td>3</td>
<td>Verification procedure for issuing blood or blood components</td>
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<td>4</td>
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<td>5</td>
<td>Notification of serious adverse reactions</td>
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<td>Requirements for imported blood &amp; blood components</td>
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<td>8 &amp; 9</td>
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<td>10, 11 &amp; 12</td>
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Annex I
- Record of data on traceability as per Article 4
  - By blood establishments
  - By facilities

Annex II – Notification of serious adverse reactions
- Part A - Rapid notification format for suspected SARs
- Part B - SARs - imputability levels
- Part C - Confirmation format for SARs
- Part D - Annual notification format for SARs

Annex III - Notification of serious adverse events
- Part A - Rapid notification format for suspected SAEs
- Part B - Confirmation format for SAEs
- Part C - Annual notification format for SAEs

- Adoption by European Commission in 2005/2006?
- Time allowed for transposition into national legislation? (not currently known, likely to be 1 year or less)

- 5 Articles
- 1 Annex

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Annex - quality system standards & specifications
1. Introduction & general principles
2. Personnel & organisation
3. Premises
4. Equipment & materials
5. Documentation
6. Blood Collection, testing & processing
7. Storage & distribution
8. Contract management
9. Non-conformance
10. Self inspection, audits & improvements
Summary of future legislative developments

- 2 EC (Technical) Directives will be adopted in 2005/06
- Deadline for national transposition is likely to be in Q4 of 2006
- The EC will develop “good practice guidelines” for the interpretation of the Community quality system standards & specifications - taking fully into account the detailed principles and guidelines of GMP
- 2 UK Statutory Instruments amending SI 2005/50
  - November 2005 - fees etc.
  - Quarter 4 of 2006 - transposition of Technical Directives
Blood Safety and Quality Regulations

Thursday 29 September 2005
Hastings Stormont Hotel, Belfast
Impact of the legislation on Operations

Operational Impact Group Report
NHS Operational Impact Group

Original group was set up as a self help sub group of the Appropriate Use Group

To provide help for Transfusion Labs

Evolved into a group sponsored by DH
Terms of Reference

To consider and make recommendations to DH and the UK Blood Services on:

(i) Whether the scope of extant requirements on hospital blood banks reflects the minimum requirements of the Directive.

(ii) Any improvements required to current arrangements with regard to systems of accreditation, ‘traceability’ and ‘adverse incident reporting’.

(iii) Any additional arrangements necessary, in order to enhance the provision of quality assurance and deliver improvements in patient outcomes.
Members of OIG

Blood Bank Managers

- Blood Services
- BSMS
- Dept. of Health
- Devolved countries

Transfusion Practitioners

- Consultant Haematologists
- Quality personnel
Scope of the Group

- Assess the impact of the Directive on hospital transfusion processes
- Include a status assessment of current practice
- Produce a prioritised action plan for improvement and identify any differences between the UK countries and if necessary incorporate interim measures.
Scope of the Group

- Assess the potential resource implications including IT, identifying where in the NHS the costs will fall and consider funding.
- Liaise and communicate with all relevant interested parties, including the Transfusion Committee networks.
- Deliver recommendations on part (i) of the terms of reference by August 2004 and on part (ii) by February 2005
Working Groups within OIG

- “Processing function”
- Quality Management Systems
- Training, Education and Communication
- Traceability
- Adverse Incident Reporting
What did OIG do?

- Fact finding enquiries
  - Face to face
  - Questionnaires
  - Met with CPA

- Ascertain current position in the UK in regard to compliance to the Regulations?

- Consider the impact
To provide clarity on the requirements
Considerations For Each Working Group

- Current Status
- Issues
- Action plan
- Possible Solutions
- Priority – short/long term
- Cost
Traceability – The Basics

- Current systems generally fail to comply

- Unequivocal recording of final fate and the identity of the patient is the ‘big’ issue

- Hospital Blood Transfusion Laboratories and ward staff need to work together to resolve the issue
Traceability - Essential Data Set

- Donation Number
- Component Type
- Blood establishment that provided the blood component
- Date provided
- Identify the patient in receipt of the blood component or the final fate if not transfused

- Issue does not guarantee receipt
- Record must be kept for 30 years
Traceability - Recommendations

- Participate in BSMS
- Unable to recommend using the patient notes
- Minimum data kept by simple paper system
- Additional data with adequate IT systems
- Transfer of stock
  - National policies
Traceability – How to Comply!

- Each hospital/Trust will need to decide their option.
- Paper and/or electronic records are acceptable.
- Information added to LIMS - unnecessary to keep the paper trail.
- Validated, audited and documented.
- Involve key stakeholders.
I think I got it located.
Traceability - Costs

- Variable
- Reported for small, medium and large
- Reported for simple and “high tech”
- Don’t underestimate “real time” non compliances
Quality Management Systems

OIG developed Quality Management System (QMS) specification – agreed by MHRA

MHRA have indicated those criteria which need to be in place by 8th November
Quality Specifications

- Quality Manual
- Access to Quality Manager
- Receipt of timely, relevant, regularly updated training (including an induction) for staff
- Controlled documentation system
- Full compliance with Traceability requirements
Quality Systems - SOPs Required

- For storage, distribution and transport of blood components (within and outside the hospital)
- Temperature controlled storage, its monitoring and management of the cold chain
- Validation and calibration of processes/equipment
- Notifying serious adverse events/reactions
- Component recall
Quality Systems - Working Towards

System for change control

Ongoing programme of self inspections
By 8th November will this be you!
Quality Systems - Costs

Increased scope and stringency of quality management in the HTL and Clinical Transfusion Process

Will require additional resource which is difficult to quantify, BUT …..

Many transfusion labs do not have a Quality Manager or access to one
Processing Activities

From 09 November 2005, you MUST be registered as a Blood Establishment to undertake any of the following:-

- Pooling cryoprecipitate
- Component irradiation
- Manipulation of Hct/removal of plasma from red cells
- Pre-operative Autologous Donation
- Collection and processing of donor granulocytes
- Splitting of components
- Washing cellular components

Determined by the MHRA
Continuation of Processing Activities – Yes or No

You only need to apply for Blood Establishment status if you want to continue doing any of the identified activities.

Concerns for supply planning purposes.

Some Transfusion Laboratories have decided to apply for Blood Establishment status.
Processing - Costs

- Inspection fees
- Irradiator decommissioning costs
- Costs for irradiated components
- Logistical implications
Education and Training

(a) ensure that personnel directly involved in the testing, storage and distribution of human blood and blood components for the hospital blood bank are qualified to perform those tasks and are provided with timely, relevant and regularly updated training;

(b) maintain documentation on … training… so that they are readily available for inspection under regulation 15.”
Education/Training-Recommendations

- Documented evidence of appropriate qualifications, supported through current job description and person spec.
- Documented evidence of training in a training record
- Training records to include date of training; details of task/procedure; details of the trainer and training review date
- Copies of any assessment criteria
- Certificates of training or competence when provided
Education/Training-Recommendations

Regulations only require training for staff involved in collection, processing, testing and distribution

- Collection of blood from the fridge = distribution – training required
- Staff will require training to achieve compliance for:
  - Traceability
  - Serious adverse reactions/events reporting
Education/Training - Costs

- Determine what is required
- Determine who requires what
- Determine who will deliver

- Transfusion Practitioner appointment

- Time to train laboratory staff
- Time to train other staff
Communication

- Formal annual statement
- Effective communication about the requirements

What has OIG provided
- Regular updates
- Countdown to compliance posters
- Presentations

You need to use the resources provided!

- Devolved countries have Implementation groups and are working on a Regional basis
Communication
Adverse Events (Haemovigilance)

- Working group consisting of:
  - OIG members
  - SHOT members
  - MHRA
  - NPSA
  - Blood services

Information will be provided today
Has OIG met their Objectives?

Yes and NO

- OIG report
  - not delivered by Feb 05
  - Delays not of our making

Made balanced recommendations that are achievable!
Has OIG met their Objectives?

Yes and NO

- Have identified the cost **BUT** unable to find the funding!
- Identified the impact
- Produced some information for the “Toolkit” to help hospitals

The proof of achievement will be evident when the compliance forms are completed!
Hopefully this no longer applies
Blood Safety and Quality Regulations

Thursday 29 September 2005
Hastings Stormont Hotel, Belfast