GUIDANCE NOTE FOR INFORMATION TO:
NHS Hospital Trusts
Foundation Hospitals
Primary Care Trusts
Strategic Health Authorities

THE BLOOD SAFETY AND QUALITY REGULATION (NO 50) 2005

Summary

1. This guidance sets out the main requirements of new Blood Safety and Quality Regulations that come into force from 8 November 2005, draws attention to their implication for hospitals involved in blood transfusions and highlights some specific aspects that need consideration in order to ensure compliance.

Background and scope

2. The Blood Safety and Quality Regulations (No 50) 2005 - made under Section 2(2) of the European Communities Act 1972 - transpose two EU Directives (2002/98/EC and 2004/33/EC) into UK law.

3. They set standards for the collection and testing of human blood and blood components and their processing, storage and distribution when intended for transfusion. Their overall aim is to ensure a comparable level of quality and safety throughout the blood transfusion process in all Member States.

Requirements

4. The Regulations require all establishments collecting and testing blood and blood components - whatever their intended purpose - and processing, storing and distributing blood or blood components when intended for transfusion, to be authorised as 'blood establishments'.

5. Blood establishments will include the UK Blood Services and any hospital units collecting and processing blood or blood components. They will be inspected and authorised by the Medicines and Healthcare products Regulatory Agency (MHRA) – the UK Competent Authority - on behalf of the Secretary of State.

6. In addition the Regulations impose some specific requirements on hospital blood banks including:
   a**) Qualifications and training** – personnel directly involved in the testing storage and distribution of human blood and blood components

for the hospital blood bank must be appropriately qualified and receive timely, relevant and regularly updated training.

b) **Traceability** - hospital transfusion laboratories must maintain the data needed to ensure full traceability of blood and blood components from point of receipt by the hospital blood bank – including the identity of the patient receiving the component or other fate if not transfused - for *not less than 30 years*

c) **Licensing** - '*processing activities'* currently carried out in some hospitals can in future only be performed in authorised blood establishments or by laboratories granted a limited blood establishment status.

d) **Reporting** - whilst the Regulations do not require the licensing or routine inspection of blood banks, annual compliance reports to the MHRA - which may be followed up by 'for cause' inspections - will be required.

e) **Adverse event/reaction** – it will be mandatory to report any serious adverse event or reaction related to blood or blood components to the MHRA and to have a procedure for the withdrawal from distribution of blood or blood components that are the subjects of such reports.

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The OIG Report

7. The Department of Health (DH) requested an NHS Operational Impact Group (OIG) to consider whether current hospital blood bank standards/practices meet the minimum requirements of the Regulations and to provide advice on any necessary improvements. The OIG report is available on the UK Blood Transfusion Services website (Chief Executive Bulletin: Issue 279, 23-28 July)

8. Its findings and recommendations are not mandatory, but are intended to assist implementation. They confirm that existing guidance - specifically HSC 2002/009 'Better Blood Transfusion' and 'Modernising Pathology Services' (DH Feb 2004) - cover the majority of the Regulation's requirements and that those hospitals already complying and observing best practice should encounter no major implementation difficulties.

9. The Report also identifies some new requirements and highlights specific areas - such as record retention, donor to patient traceability, quality assurance, the need to license 'processing' activities currently carried out by some hospital laboratories, staff training and mandatory adverse event reporting - that may require improvements.

10. Whilst the OIG suggest that additional posts may be helpful, individual NHS Trusts and Foundation hospitals are best placed to consider alternatives and decide how the Regulations should be implemented, bearing in mind current practices, existing structures and available

resources. The administrative, financial and operational impact will depend on how far hospitals are compliant with current requirements and best practice.

11. OIG also supports the development of IT solutions to improve traceability. Whilst some existing laboratory systems may offer that functionality - and manual alternatives are also available - Trusts should particularly note that pathology is an "additional" service rather than a core requirement under the LSP contracts and therefore is not currently funded through currently the NHS Connecting for Health. programme

Implementation

12. Hospitals providing blood transfusions are advised to review - and if necessary revise - their processes and procedures in order to ensure that they comply with the requirements of these Regulations. The implementation-planning toolkit available as part of the OIG report should assist and specific advice and information may also be available from the National Blood Service (NBS) and the MHRA.

13. Hospitals wishing to undertake any of the following collection and processing activities will also need to consider applying to MHRA for a authorisation as a 'Blood Establishment' (details and forms available on MHRA website: www.mhra.gov.uk) or explore alternative provision through their Blood Service provider to ensure that supplies are not disrupted:
    a) Whole blood collection
    b) Pre-deposit autologous whole blood donation
    c) Testing donor samples
    d) Apheresis collection of components
    e) Processing whole blood into red cells, platelets, granulocytes, fresh/ frozen plasma, recovered plasma (for discard), cryoprecitate, cryoprecitate depleted plasma or buffy coat.
    f) Processing components into methylene blue, treated plasma, irradiated components, washed components, splitting into paediatric packs, pooling cryoprecipitate or manipulation of haematocrit.

14. Hospitals should note that an authorisation is not required for storing blood and blood components, performing cross matching, defrosting frozen components, or distributing blood and blood components.

Sanctions

15. Should the MHRA consider that a blood establishment or hospital blood bank has failed to comply with the Regulations or is maintaining working practices that call into doubt the safe administration of blood or blood components it may suspend or revoke an authorisation or issue a notice prohibiting any specified activity, the ultimate sanction for non compliance being criminal proceedings.

SHOT arrangements

16. Existing voluntary reporting arrangements under the Serious Hazards of Transfusion (SHOT) scheme are to continue as they enjoy widespread professional support and have a wider scope. To harmonise and simplify reporting a web based facility incorporating SHOT information requirements is at an advanced stage of development by MHRA.