Informing Healthcare/Welsh Blood Service
Traceability & EU Directive Workshop
15 March 2005

Purpose

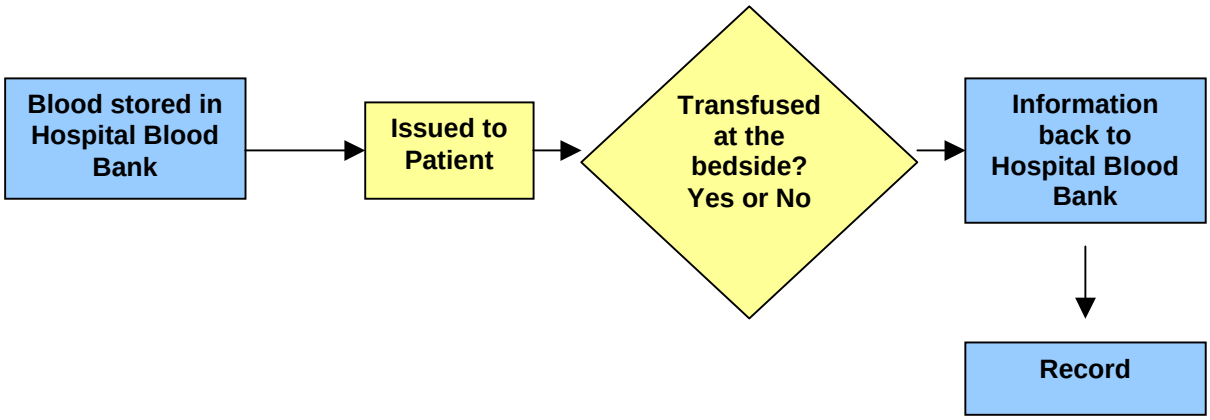
On 08 February 2005, the Blood Safety and Quality Directive 2005 became Law in the UK, which has a number of significant implications for hospitals and blood services. Its aim is to ensure a high level of human health protection by setting standards of quality and safety for the collection, testing, processing, storage and distribution of blood and blood components where intended for transfusion.

The UK Government has taken up the option of derogating the date of implementation until 08 November 2005. This means that UK Blood Services and all Hospital Blood Banks have 8 months to achieve compliance with the requirements of these Directives.

The purpose of the workshop was to raise awareness of the important points in the Directive, and define a practical approach for Trusts to deliver compliance.

Summary Notes

Just over 60 Trust managers and healthcare professionals, from across Wales, generated a wide ranging discussion around shortfalls in the current process, what needs to be done to comply and potential IT solutions. The day concentrated on the pathway for all blood and blood components starting with:



Overall conclusion from the day was that current systems did not have the structure or control measures in place to ensure compliance.

Key issues and suggested actions are as follows:

Issues	Suggested Actions
1. Responsibility	Ultimately lies with the Trust Chief Executive, but: • Agree a project lead at senior management level together with a project plan • Trust transfusion team/committee endorsed by the Executive Board, to be given the authority to implement changes to address compliance and identify staff and other resources needed • Need to assess whether compliance with the Directive is a professional responsibility (for Nurses), similar for example to controlled drugs • Training needs to stress legal implications of Directive • Encourage WAG to issue a WHC on the issue • Approach postgraduate dean
2. Awareness	• Raise within clinical governance arena, particularly clinical risk issues linked to Welsh Risk Pool • Need to identify key personnel for initial awareness training • Needs to be part of the organisation's induction and training programme, thinking differently about delivery such as e-learning, folder learning and work-based training • Think of publicity stunts, such as launch day, roadshows, newsletters, stalls, poster campaigns • Need to share good practice across sites • Use journal publications to strengthen reason for Directive
3. Process	• Risks of non-compliance become greater away from the lab environment • Key personnel need to be involved in agreeing the way forward, including blood bank staff, portering, receptionists, ODAs/ODPs, nursing and medical staff

Process continued	• Potential short term solutions regarding: i. Paper trail returned to the laboratory with electronic data hold ii. using 'Telepath' or other software modifications similar to North Glamorgan NHST with point of care recording iii. electronic patient record is considered the ultimate solution • Need to audit compliance to support any corrective action needed and reported to clinical governance forum • Minimum dataset requirement is at point of transfusion, although there are quality control issues with regards to other parts of the process, such as within lab, transfer to the blood fridge, actions of the assigned person, blood not used, which will also be part of the Directive under the daughter directives still to be finalised
4. Documentation	• Basic dataset points are lab⟶ward⟶lab • Think about the requirements of the data collection, which as a minimum needs to ensure strict vein-to-vein traceability and may only warrant a tick-box to demonstrate compliance • Review the need for All Wales policies, including defining start of transfusion • Keen to develop a simple All Wales data form for consistency, possible solution: i. Modification of the compatibility form ii. introducing 'two' part transfusion record to include actual time of transfusion peeling off section from the compatibility label (one copy back to lab) iii. register (as the controlled drugs register) • Agreed information can't be kept in the patient record due to the length of time (30 years), information is to be kept compared to patient notes

5. Resources	• Defined cohort of trainers to educate all key personnel by November 2005 with the Transfusion Practitioner (TP) to facilitate. Identify, in the absence of a TP who will lead on this • Additional staff at the laboratory end to process returned data • Teams to tap into IHC to support any hardware infrastructure • Use Welsh Blood Service team for support and advice • Compliance audit could sit within blood bank but will need adequate resourcing, may be from the audit department • Team/committee members need to be given adequate time to address what needs to be done and resources where identified to support the method of compliance