TRANSFUSION TRACEABILITY

1. Introduction

1.1. The Blood Safety and Quality Regulations 2005 transpose the European Blood Directive into United Kingdom law. This new law imposes significant new requirements on hospital transfusion laboratories and the clinical transfusion process.

1.2. The Regulations require “unambiguous traceability” of all blood and blood components from donor to patient and vice versa or final fate if not transfused.

1.3. The law demands that evidence of the final fate of every blood component be retained and accessible for 30 years.

1.4. The procedure described in this Standard Operating Procedure (SOP) has been designed to allow a signed record of the clinical staff who witnessed the transfusion to be returned to the blood transfusion laboratory who issued the blood component.

1.5. This record will be used by the laboratory to complete the computer record of the transfusion and will itself be stored and kept available for 30 years. The returned label may be kept, scanned or input into a computer system differently by different users of the SOP.

1.6. This SOP has been written to describe the basic use of the new traceability label and does not preclude individual laboratories from having different methods of selecting blood components for transfusion, retrieving the traceability label or storing the traceability label.

1.7. In the same way, the consumables and practices in laboratories and wards may not be exactly the same as shown in this SOP. In that event the SOP should be modified to reflect local practice.

1.8. Labels shown are purely for illustrative purposes.

2. In the Blood Transfusion Laboratory

2.1. The request for transfusion is received in the laboratory as normal.
2.2. Pretransfusion testing takes place as at present.

2.3. Once compatible donations are selected, the new traceability label is printed.

2.4. The label is checked and then attached to the correct donation by means of a tamper-proof tie.

2.5. The blood pack is over-wrapped and sent to the relevant blood fridge or to the ward for transfusion.
3. **Issue of Blood for Transfusion**

3.1. When the blood is required for a patient, the staff member collecting the unit checks the label on the blood pack with the blood request form. Any discrepancies are investigated and resolved before proceeding.

3.2. The staff member records the blood donation number, patient’s name, clinical area and time on the blood fridge record sheet.

4. **In the Clinical Area**

4.1. At the patient’s bedside, the patient is asked to verbally confirm their full name and date of birth. The two practitioners confirm the patient’s details against the traceability label and patient’s wristband. Check the pack for expiry date and any leaks, discolouration or clumping. If there are any discrepancies the transfusion should not proceed. Contact the Hospital Transfusion Laboratory.
4.2. If the checks are satisfactory, practitioner(1) signs the pink section of the traceability label before commencing the transfusion.

4.3. If the checks are satisfactory, practitioner(2) signs the pink section of the traceability label before commencing the transfusion.

4.4. Set up transfusion as normal.

4.5. Once transfusion is underway, remove the completed “peel-off” pink portion of the traceability label (which has been signed by both practitioners).
4.6. Attach the pink “peel off” portion in the relevant place in the patient’s notes.

4.7. Both practitioners must sign the prescription form and, when completed, file in the appropriate place in the patient’s records.

4.8. Once the transfusion is underway the practitioner separates the blue “return to laboratory” section of the traceability label.

4.9. The practitioner signs and completes the blue “return to laboratory” section of the traceability label, confirming that the blood component identified on the traceability label was transfused to the patient named on that label.
4.10. The practitioner places the tear-off label in the container provided for return to the blood transfusion laboratory.

5. **Back in Blood Transfusion Laboratory**

5.1. Laboratory staff member receives completed labels from wards.

5.2. Donation number barcode on the traceability label is wanded into computer system to electronically confirm the transfusion event in the patient’s record.
5.3. The blue peel off section on the traceability label is attached to the reverse of the request form. Alternatively the entire returned label can be filed or scanned. In any event the record needs to be retained for 30 years.

6. **Non Return of Tags**

6.1. The Laboratory computer system has been configured to produce a report which lists components which have been assigned for use but do not have an entry for return to stock or final fate. These non-return reports are produced and followed up daily. Agreed corrective action will be put in place and ongoing problems will be referred to the Hospital Transfusion Committee and elevated upwards to the Chief Executive if necessary.
7. Appendices

7.1 Appendix 1 - Traceability Label (front)

This is a mock up for information only.
It is not to scale, barcodes are illustrative.

<table>
<thead>
<tr>
<th>Surname:</th>
<th>Patient</th>
<th>Forename:</th>
<th>Any</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOB:</td>
<td>09092005</td>
<td>Gender:</td>
<td>Male</td>
</tr>
<tr>
<td>Local Identifiers:</td>
<td>17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Street Name</td>
<td></td>
<td>Town</td>
<td></td>
</tr>
<tr>
<td>Postcode</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Identity No:</td>
<td>0909055223</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date/Time Required:</td>
<td>020905</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Blood Group:</td>
<td>O Rh Negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Component:</td>
<td>Red Cells</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donation Number:</td>
<td>G101 605 225 663 P</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donor Number:</td>
<td>G101 605 225 663 P</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Component:</td>
<td>Red Cells</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Special Requirements:</td>
<td>Infuse through a blood warmer, Irradiated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Once transfusion has been confirmed, you must send the completed section below to the Hospital Transfusion Laboratory. This is a legal requirement.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Surname:</th>
<th>Patient</th>
<th>Forename:</th>
<th>Any</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Identity No:</td>
<td>0909055223</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory Number:</td>
<td>2222222</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donation Number:</td>
<td>G101 605 225 663 P</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Given</td>
<td></td>
<td>Time Given:</td>
<td></td>
</tr>
<tr>
<td>I confirm the above patient received this component- Sign and Print Name</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Content should remain unchanged but placement of boxes, fonts etc will change.
7.2 Appendix 2 - Traceability Label (back)

This is a mock up for information only.

**PRE ADMINISTRATION**

**STEP 1:** Check the blood component has been prescribed  
Check any special requirements e.g. irradiated, CMV negative  
Check concomitant drugs e.g. diuretic

**STEP 2:** Check and document baseline observations

**STEP 3:** Check expiry date and time of component,  
Check pack for leaks, discolouration or clumping

**ADMINISTRATION**

**STEP 1:** Ask the patient to tell you their Surname,  
Forename and Date of Birth, be especially vigilant with unconscious or compromised patients, refer to your local hospital policy

**STEP 2:** Check their Surname, Forename, Date of Birth and Patient Identity Number against their wristband and the label

**STEP 3:** Check that the information on the compatibility label matches the details on the blood component i.e donation number, blood group

If there are any discrepancies – **DO NOT PROCEED** - contact your Hospital Transfusion Laboratory

If you suspect a transfusion reaction - **STOP** the transfusion immediately, seek medical advice, and contact the Hospital Transfusion Laboratory

Under the Blood Safety and Quality Regulations 2005 **IT IS A LEGAL REQUIREMENT** that this section of the label be completed and returned to the Hospital Transfusion Laboratory

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