# IV outlineVALIDATION OF TRANSFUSION ORDER COMMS/EPR SOLUTION

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**TRANSFUSION SERVICES**

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| **Question**  **Number** | **Question** | **Evidence requirement** | **Validation passed** | **Comments** |
| **1** | Essential System Requirements |  |  |  |
| 1.1 | There must be bidirectional interfaces between the EPR, the LIMS and Electronic blood management systems. | All interfaces tested using fake patient:  5 orders (G&S, Red cell, platelets, IVIg and anti-D) placed on EPR and demonstrated to arrive in LIMS  Above orders completed on LIMS and results/products demonstrated in EPR  Evidence that interfaces are visible and can be seen to be active  Evidence that interfaces can be re-started by laboratory staff |  |  |
| 1.2 | The order comms system must be capable of including orders for all blood components and products available at the Trust  The system must be capable of including additional, new components and products as they become available | EPR includes ordering system for:  Red cells (adult and paediatric)  FFP(adult and paediatric)  Platelets(adult and paediatric)  Cryo(adult and paediatric)  Granulocytes  Albumin (20% and 5%)  IVIg  Anti-D  Anti-tetanus  Clotting factors  PCC  Praxbind  Lyoplas  Octaplas  Fib conc |  |  |
| 1.3 | To ensure running security and performance, supplier must state:   * number of concurrent users allowed on system at any one time; * maximum transaction rate to be supported; * resilience to single point of failure. | Evidence that this information has been obtained and is accepted |  |  |
| 1.4 | The system must support multiple environments with a minimum of two environments to allow a separation of live and validation/training environments.  Each environment must be completely independent and must be kept fully updated in parallel with the live system.  The supplier must specify the number and type of environments supplied | Evidence of multiple environments  All validation on the test system must be retained – evidence of where and how this information is retained |  |  |
| 1.5 | The maintenance requirements of the new system must include:  ● clear definition of services to be provided;  ● responsibilities and duties of the hospital transfusion laboratory (customer);  ● responsibilities and duties of the hospital IT department;  ● responsibilities and duties of the system supplier;  ● key Performance Indicators (KPIs);  ● problem management procedures;  ● disaster recovery.  ● definition of service period and termination of agreement;  ● warranties;  ● review periods.  Supplier must confirm that requirements are met and provide details of these arrangements | This information must be retained by the lab and IMT – evidence required by SLA with IMT department |  |  |
| 1.6 | The supplier must provide change management procedures; release notes must be supplied in a timely manner to allow for validation of the changes in the test system prior to release into the live system | Assurance from EPR that release notes are supplied |  |  |
| 1.7 | All upgrades to the system must be supplied free of charge | Evidence from My Care team |  |  |
| 1.8 | The system must include access control ensuring that critical process steps are only available to authorised staff  There must be variable levels of access dependent on the role of the individual  It must be possible to assign access rights to individual staff independent of their job title but dependent on their actual role within the Trust, this must be user configurable  There must be a time-out function - please state if this is user configurable or state set time period  Access to the transfusion system should link to the Electronic Staff Record (ESR) system, access should be limited to staff with in date transfusion training records on the ESR.  The system should alert staff when accessing the system if their transfusion training record is due to expire within a user configurable time period  The system should link to the ESR transfusion training package if a user with expired training accesses the system, the system should provide an option to complete the training at that point | Test critical functions including:  Red cells  ordered by medic  ordered by clinical nurse specialist  cannot be ordered by registered nurse  Cannot be ordered by unregistered staff  Anti-D  Ordered by medic  Ordered by midwife  Cannot be ordered by registered nurse  Cannot be ordered by unregistered staff  FFP  Ordered by medic  Ordered by midwife  Cannot be ordered by registered nurse  Cannot be ordered by unregistered staff  G&S  Ordered by medic  Ordered by midwife  Ordered by registered nurse in surgical/orthopaedic outpatients  Cannot be ordered by other registered nurse  Cannot be ordered by unregistered staff  Evidence that system alerts staff when training due to expire in 3 months –  Test for 5 staff using:  Test ordering module (G&S, Kleihauer, DAT)  Test for 5 staff using blood ordering module (red cells, anti-D, IVIg) |  |  |
| 1.9 | The system must support the ordering of components/products including capture of information required by the transfusion laboratory, including (at a minimum):   * Patient demographics (surname, forename, DoB, NHS and hospital number) * Location/ward * Reason for request * Underlying diagnosis * Type of request – group and save, crossmatch, FMH, DAT * Type of component/product required * Date/time required * Urgency of request * Name and contact details of requestor * Sample requirements | Demonstration that system captures and retains information (confirmation with 5 orderable tests and 5 blood components/products):   * Patient demographics (surname, forename, DoB, NHS and hospital number) * Location/ward * Reason for request * Underlying diagnosis * Type of request – group and save, crossmatch, FMH, DAT * Type of component/product required * Date/time required * Urgency of request * Name and contact details of requestor * Sample requirements |  |  |
| 1.10 | The system must support a process for emergency requesting of components/products in the event of a massive haemorrhage, this must include a fast and simple process for ordering:   * Massive haemorrhage pack (component type and number user configurable) * Trauma code red pack (component type and number user configurable) | Demonstration that the system can be used for emergency request for (test using 5 patient issues):  Red cells (emergency issue from fridge using patient ID)  MH (4 red cells and 2 FFP)  Trauma code red (2 red cells and 4 FFP)  PCC |  |  |
| 1.11 | The emergency request process, as described above, must include an automated escalation process to communicate the requirement to the laboratory staff (eg automated trigger for phone call or bleep to specified number).  Please state how this is achieved | Confirmation that system alerts user to requirement for:  Red cells (emergency issue from fridge using patient ID)  MH (4 red cells and 2 FFP)  Trauma code red (2 red cells and 4 FFP)  PCC  Note: alert for emergency red cell or PCC issue at fridge may be via Electronic blood management , this is acceptable |  |  |
| 1.12 | The system must support hyperlinks to Trust or external documents related to the transfusion process (eg Transfusion Policy, guidelines for massive haemorrhage, blood component and product appropriate usage) | Demonstration that EPR has hyperlinks to the following:  Transfusion policy in all transfusion modules (test and blood orderables)  Exeter clinical laboratory website for-  Test orderables (G&S, Kleihauer, DAT, cffDNA)  BCSH guidelines for:  Red cells  FFP  Platelets  Granulocytes  RD&E guideline for:  Reversal of anticoagulation  PCC  Praxbind  Massive haemorrhage  Trauma code red  National guidelines for:  IVIg  Anti-tetanus |  |  |
| 1.13 | The system must interface to the Electronic blood management system to identify any blood components/batch products that are ready for collection at the time of request, this process must include the following features:   * Identification of the location of the components/products * Only identify the component/product type requested * Produce a pick-up slip compatible with the Electronic blood management system for collection of the component/product * Capability to identify red cells that are allocated or unallocated but suitable for the patient | Test using the following products:  Red cells  FFP  Platelets  Cryoprecipitate  Fib conc  Anti-D  IVIg  Albumin  PCC  Praxbind  Clotting factors  Octaplas  Evidence for 5 patient that information includes:   * Identification of the location of the components/products * Only identify the component/product type requested * Produce a pick-up slip compatible with the Electronic blood management system for collection of the component/product * Capability to identify red cells that are allocated or unallocated but suitable for the patient |  |  |
| 1.14 | The system must be capable of distinguishing between a request for red cells that will result in transfusion and a request for red cells for standby (for example for cover during an operative procedure) that will not necessarily result in transfusion | Confirmation that functionality exists for following scenarios:  Red cells on standby for next day  Red cells on standby for up to 72 hours  Platelets on standby for next day  Confirmation that this orderable does not result in generation of:  Prescription for administration  Pick-up slip for collection  Confirmation that information relating to the request, including the unique numbers of any blood components, is retained within EPR  Confirmation that information in EPR relating to blood component is clear that the component was not used for this event  Test using 4 components that have been ordered for standby and now required for administration:  EPR generation of prescription  EPR generation of pick-up slip  EPR/Electronic blood management administration process  Components fated against patient record in EPR , Electronic blood management and LIMS |  |  |
| 1.15 | When a request is generated for red cells for confirmed transfusion the system must be capable of generating the prescription | Confirmation of prescription using 10 patients:  Red cells for transfusion:  Emergency  Same day  Next day  Up to 72 hours |  |  |
| 1.16 | The prescription system must include selectable administration times based on component type  This process must include a maximum administration time for each component type | Confirmation that administration time:  Is configurable per components (red cells, FFP, platelets, cryo, granulocytes)  Cannot exceed 4 hours from time out of controlled storage for red cells  Cannot exceed 4 hours from time out of controlled storage for platelets  Cannot exceed 4 hours from time out of controlled storage for FFP  Cannot exceed 30 minutes from time out of controlled storage for cyo  Cannot exceed 4 hours from time out of controlled storage for octaplas |  |  |
| 1.17 | The prescription system must include a process for identification of any special requirements (eg irradiated, CMV negative, washed, administration of anti-histamine or anti-pyretics prior to transfusion) | Confirmation that the following can be added to the order:  Irradiated – red cells and platelets  CMV negative – red cells and platelets  Washed – red cells and platelets  Anti-histamine  Anti-pyretics  Confirmation that EPR has hyperlink to guidance for :  Irradiated  CMV neg  Confirmation that requirement for irradiated is linked to all blood orders for the patient  Confirmation that removal of irradiated retains full audit trail including:  Date/time  Individual  Reason for removal  Confirmation that CMV negative is automatically added to:  Blood component order for planned non-urgent transfusion for woman with current pregnancy  Neonates up to 28 days post expected date of delivery  Granulocytes for CMV seronegative patients  Intrauterine transfusions  Exchange transfusion  Confirmation that irradiated requirement is automatically added to :  Allogeneic haemopotietic stem cell transplant recipients from the time of conditioning therapy, continues while the patient is receiving GvHD prophylaxis. If chronic GvHD present or taking immunosuppressants irradiated components required indefinitely  Allogeneic bone marrow or stem cell donors, 7 days prior to and during the harvest  Autologous stem cell recipients from conditioning therapy until 3 months post-transplant (6 months if total body irradiation is used)  Patients undergoing bone marrow or peripheral blood stem cell harvesting for future autologous reinfusion during and for 7 days before harvest  All donations from HLA matched donors or first or second degree relatives (even if the recipient is immunocompetent)  Severe T-Lymphocyte immunodeficiency syndromes  Patients with Hodgkin lymphoma  Patients treated with purine analogue drugs  (Fludarabine, Cladribine, Deoxycoformicin, Bendamustine and Clofarabine)  Patients treated with Alemtuzumab and/or Rabbit Anti Thymocyte Globulin (ATG)  Intra-uterine transfusions (IUT)  Exchange transfusion in neonates  Top-up transfusion in neonates (if there has been an IUT, exchange transfusion or if the donor is a first or second degree relative) until 6 months after the expected delivery date.  Platelets transfused in utero to treat alloimmune thrombocytopaenia and top up platelet transfusions until 6 months after the expected date of delivery  Granulocyte transfusion |  |  |
| 1.18 | For any request for group and save or crossmatch for red cells, the system must interrogate the LIMS system and inform the user whether there is a valid transfusion sample in the laboratory  Sample validity must be user definable in accordance with BCSH guidance (eg <72 hours old)  The system should present the user with the following information:   * Sample validity (valid sample or requires new sample) * Blood group * Antibody screen (negative or specificity of any atypical antibodies) * Information regarding any potential delays in blood provision in the presence of a positive antibody screen * Any patient related sample flags (eg patient requires crossmatch at reference centre, 2 samples required)   If there is no valid sample in the laboratory the system must generate a request for a sample collection event | Confirmation using 5 fake patients:  Request for G&S – valid sample available system informs user of validity date. User has option to take another sample or escape from request  Request for G&S – no valid sample, user proceeds to take sample module  Request for red cells - valid sample available system proceeds to:  Input clinical indication codes  Confirm Hb within 24 hours  If Hb 70-100 allows 1 unit request  If Hb<70 allows more than 1 unit request  If for standby confirms request against ASBOS requirements and antibody positive status  Proceeds to:  Electronic blood management enquiry showing remote allocation units available  Electronic blood management enquiry showing remote allocation/labelled units available  EPR generates a request for red cells:  If no red cells available on Electronic blood management EPR generates a request – request transferred to LIMS  Sample validity extracted from LIMS – 72 hours  Override facility for up to 7 days – must be authorised by consultant haematologist  Confirm EPR left had screen displays:  Blood group  Sample validity – stating date/time valid to  Antibody screen  Information regarding any potential delays in provision of blood  Status of any samples in process in the laboratory  Any patient flags relating to sample as reported at last test  At request for red cells, if no valid sample EPR generates a request for a sample collection  At request for red cells, if valid sample EPR does not generates a request for a sample collection  At request for red cells, if sample in process in lab EPR generates a request for a sample collection |  |  |
| 1.19 | For any request for FFP, cryoprecipitate, platelet concentrate and/or Octaplas, the system must interrogate the LIMS system and inform the user whether there is an historic transfusion sample in the laboratory  If there is no historic blood group in the laboratory the system must generate a request for a sample collection event | User places request for – FFP, platelets, Octaplas, cryoprecipitate, anti-D:  EPR interrogates LIMS for blood group (ABO/D):  Blood group present – order can be placed in accordance with triggers and clinical indication codes  No blood group present – order can be placed  EPR generates request for sample collect  Message to user that blood order cannot be fulfilled until the sample has been processed |  |  |
| 1.20 | The system must interface to the LIMS to transfer the request to the LIMS system for laboratory action | Confirmation that all test requests and blood orders are received in the LIMS:  G&S  Kleihauer  DAT  Antenatal G&S  Phenotype (Rh/K)  cffDNA for RhD  Cold agglutinin screen  Red cells  FFP  Cryo  Platelets  Octaplas  Albumin (20% and 5%)  IVIg  Anti-D  Anti-tetanus  C1 esterase  PCC  Factor VIII  Factor IX |  |  |
| 1.21 | The system must operate in accordance with all national recommendations for blood transfusion, including, but not limited to BCSH, BSQR, ISO15189, Department of Health | Covered by this validation – no further evidence required |  |  |
| 1.22 | The system must be capable of receiving information from the LIMS/Electronic blood management regarding release of all blood components/products, including the following as a minimum:  • Product unique identification number  • Product expiry date  • Date/time of laboratory issue  • Location of anti-D  • Dereservation date of product | Confirmation that EPR receives and retains information for all components/products:  Product unique identification number  • Product expiry date  • Date/time of laboratory issue  • Location of anti-D  • Dereservation date of product   * Fate of product   For the following products:  Red cells  FFP  Cryo  Platelets  Octaplas  Albumin (20% and 5%)  IVIg  Anti-D  Anti-tetanus  C1 esterase  PCC  Factor VIII  Factor IX |  |  |
| 1.23 | **Pick up slip requirement, must be compatible with Electronic blood management Courier**  Must have legible print  Must have a functional barcode that can be read by the Safe-Tx PDA device  Must contain-  Patient surname in uppercase  Patient forename in uppercase  Hospital number barcoded and eye readable  NHS number barcoded and eye readable  Date of birth in format DD-ABC-YEAR  Product type  Quantity of product to be collected  Location to collect from  Location to deliver to | Confirmation that pick-up slip contains all relevant information  Confirmation that pick-up slip can be used at Electronic blood management locations to collect products:  Issue fridge  Platelet agitator  Batch issue location  Confirmation that pick-up slip can be used on IOS device:  Note – unclear if this will work in place of paper copy |  |  |
| 1.24 | **Interfacing Data**: The blood bank system should interface discrete Unit number, Product Code, Blood Type and Expiry Data.  o   **Label Creation**: The labels should be produced in accordance to the international standard and have a unique barcode for each of the interfacing data. |  |  |  |
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| **2** | Patient Blood Management |  |  |  |
| 2.1 | It is a requirement of the Blood Safety and Quality Regulations (as  amended) (BSQR 2005) and the EU Directive 2001/83/EC (EU 2001) that records are retained allowing tracing of all blood components and batch products from source to recipient or final fate and vice versa.  The system must support fating of units against an individual patient record electronically via the Electronic blood management system and/or the LIMS  Please state how this is achieved | Confirmation that EPR retains the fate of components and products  Test using:  Red cells  FFP  Cryo  Platelets  Octaplas  Albumin (20% and 5%)  IVIg  Anti-D  Anti-tetanus  C1 esterase  PCC  Factor VIII  Factor IX  Confirm that EPR clearly states the component/product has been transfused to the patient when this status is returned from Electronic blood management Tx/LIMS  Confirm that EPR clearly states the component/product has not been transfused when Electronic blood management /LIMS returns the status:  Returned to stock  Disposed |  |  |
| 2.2 | The fating system must clearly demonstrate that an individual blood component or batch product has been transfused to a patient  Components/products that have been allocated but not transfused to the patient must either be clearly marked as not transfused, or disassociated from the patient record.  Please state how this is achieved | As above – tested using all components/products |  |  |
| 2.3 | Information relating to autologous blood usage (cell salvage) must be electronically recorded in the patient record, this must include (at a minimum):   * date/time of cell salvage event * Collection only or re-infusion * Volume of cells re-infused * Operation type * Surgeon identification * Adverse events * Pre-operative Hb   This information may be electronically received directly from the cell salvage devices or from the Electronic blood management or the LIMS, please state how this is achieved | Confirmation that information from the cell salvage devices can be extracted from Electronic blood management /LIMS and retained in EPR  Information must include:   * date/time of cell salvage event * Collection only or re-infusion * Volume of cells re-infused * Operation type * Surgeon identification * Adverse events * Pre-operative Hb |  |  |
| 2.4 | The system must include a user configurable report generation system that includes the following reports (at a minimum):   * Patient blood management history, including allogeneic blood, autologous blood, tranexamic acid use, intravenous or oral iron use * Allogeneic transfusion history linked to haemoglobin result over defined time periods * Intravenous/oral iron use linked to haemoglobin result over defined time periods * Intravenous immunoglobulin use linked to Ig trough levels over defined time periods * Human albumin use linked to albumin levels over defined time periods * Blood component use linked to TEG/ROTEM results, for individual patients or for individual component/product types * Anti-D use linked to potentially sensitising event type * Inappropriate requests generated linked to location, users and components/products * Reports on rule override, for defined period, locations, component/product type, individual requestors * Reports on cold chain excursions for defined time periods, locations, component/product type * Cell salvage reports for defined time periods, surgery type, surgeon, pre-operative Hb, adverse events * Emergency component/product usage for defined time period, location, component/product type, requestor identity * Trauma code red component/product usage for defined time period, location, component/product type, requestor identity * Blood product usage (batch products) for defined time period, location, component/product type, requestor identity * Incomplete IVIg follow up reports | Confirmation that all reports can be generated:   * Patient blood management history, including allogeneic blood, autologous blood, tranexamic acid use, intravenous or oral iron use * Allogeneic transfusion history linked to haemoglobin result over defined time periods * Intravenous/oral iron use linked to haemoglobin result over defined time periods * Intravenous immunoglobulin use linked to Ig trough levels over defined time periods * Human albumin use linked to albumin levels over defined time periods * Blood component use linked to TEG/ROTEM results, for individual patients or for individual component/product types * Anti-D use linked to potentially sensitising event type * Inappropriate requests generated linked to location, users and components/products * Reports on rule override, for defined period, locations, component/product type, individual requestors * Reports on cold chain excursions fordefined time periods, locations, component/product type * Cell salvage reports for defined time periods, surgery type, surgeon, pre-operative Hb, adverse events * Emergency component/product usage for defined time period, location, component/product type, requestor identity * Trauma code red component/product usage for defined time period, location, component/product type, requestor identity * Blood product usage (batch products) for defined time period, location, component/product type, requestor identity * Incomplete IVIg follow up reports   State any other reports generated by EPR |  |  |
| 2.5 | The reports generated must be available in multiple formats including bar charts, line graphs, crosstabs | Confirm formats of reports:  Evidence may be retained electronically and/or printed  Confirm that reports can be exported to network drives for long term retention |  |  |
| 2.6 | The system must allow for individualised requesting of allogeneic blood transfusion for chronically transfused patients based on individual patient requirements and dependent on haemoglobin levels.  This process must include warning flags if the request is non-compliant with the set requirements, and an override system with full audit trail | Confirmation that patient individualised care can be set up within EPR  Use fake patient with haematology malignancy:  Patient 1 – set system to order:  1 unit if Hb between 90-100  2 units if Hb <90  No units if Hb>100  Hb must be <7 days with no transfusion  Patient 2 – set system to order:  1 unit if Hb between 80-100  2 units if Hb <80  No units if Hb>100  Hb must be <7 days with no transfusion  Confirmation that override facility exists and records:  Reason for override  Individual  Date/time of override  Confirmation that override escalates:  Can be extracted via a report  Generates an email/flag to HTT |  |  |
| 2.7 | The system must support a formal pre-transfusion risk assessment for transfusion-associated circulatory overload (TACO), in accordance with SHOT recommendations | EPR uses information about the patient to assess TACO risk:  Age > 70 years although TACO is seen in younger  patients  Concomitant medical conditions e.g.  - cardiac failure  - renal impairment  - fluid overload  - hypoalbuminaemia  Low body weight  Too rapid transfusion  If the triggers are identified EPR generates message to clinician making order:  What do we want it to say? |  |  |
| 2.8 | The system must support weight-adjusted red cell dosing to guide the appropriate number of units required for all non-bleeding adult patients |  |  |  |
| 2.9 | The system must support weight-adjusted red cell dosing to guide the appropriate volume (mls) required for all paediatric and neonatal patients | Confirmation that if patient <16 years red cell orders are generated in mls *not* units  Confirmation that set maximum volumes cannot be exceeded:  What shall we set the maximum volumes at? |  |  |
| 2.10 | The system must include a formal record of patient consent, including details of the medical personnel obtaining consent.  In the event of retrospective consent, a reminder system must be in place to ensure that appropriate personnel confirm consent has been obtained |  |  |  |
| 2.11 | The system must support identification of patient who refuse blood transfusion, this must include details of which components/products (if any) the patient will accept | Confirmation that EPR includes field for patients that refuse blood  Confirmation that this refusal can be restricted to certain components/products , including:  Red cells  FFP  Cryo  Platelets  Octaplas  Albumin (20% and 5%)  IVIg  Anti-D  Anti-tetanus  C1 esterase  PCC  Factor VIII  Factor IX  Confirmation that this is flagged to the user at component/product order if non-accepted component/product is selected  Confirmation that this is not flagged to the user at component/product order if accepted component/product is selected  Confirmation that the accepted and non-accepted components/products can be amended  Confirmation that amendment has full audit trail:  Individual making the amendment  Date/time of amendment  Reason for amendment  Confirmation that refusal of blood components/products is flagged to the user when cell salvage is ordered |  |  |
| 2.12 | The system must support a single unit transfusion policy for red cells for stable, non-bleeding adult patients.  This must include a process for ensuring that a second unit cannot be requested without a post transfusion haemoglobin result  The post transfusion haemoglobin result must be input electronically from the LIMS or from an interfaced POCT device  A fully auditable override process must be in place if subsequent red cell transfusion is required in the absence of a post-transfusion haemoglobin result, this must include the identity of the requestor and the clinical justification for the override | Confirmation that red cell ordering process for adult patients has separate process for:  Patient actively bleeding - allows order of >1 red cell unit  Major Haemorrhage – generates order for 4 red cells and 2 FFP (pack 1)   * Generates 4 red cells and 4 FFP (pack 2) * Generates order for 4 red cells, 4 FFP and 1 platelet (pack 3)   Trauma Code Red – generates order for 2 O Neg red cells and 4 A FFP)  This should be picked up separately for age/gender rules  Other orders must conform with single unit policy:  Confirm that system restricts red cell ordering to:  1 unit if Hb>70  No units if HB>100  2 units if Hb<70  Confirm that system allows order of subsequent red cell unit if post transfusion Hb <90  Confirm that system does not allow order of subsequent red cell unit if post transfusion Hb >100  Confirmation that post transfusion Hb can be extracted from Beaker and used in rule base  Confirmation that post transfusion Hb can be manually input and used in rule base – this needs a confirmatory step that Hb has been measured by POCT  Confirm of override feature with full audit trail:  Individual overriding  Date/time of override  Reason for override |  |  |
| 2.13 | A clinical advisory service supporting the decision to transfuse process, based on transfusion triggers must be provided. This must be available for all blood components and batch products, the triggers must be user configurable based on:   * component/product type * clinical reason for request * patient underlying diagnosis * patient information (test results)   There must be an override feature with full audit trail including the requestor identity and clinical justification for override | Confirmation that EPR can use patient information within the system to guide clinical decision support:  Use national indication codes and check that they are mapped acceptably in EPR  Confirm that the following test results can be extracted from Beaker and used in clinical advisory mode:  Hb  Platelet count  PT  APTR/APTT  Albumin level  Ig level  Test clinical advisory mode all relevant national indication codes  Test using test results within acceptable level (state patients tested)  Test using test result outside acceptable level (state patients tested)  Confirm of override feature with full audit trail:  Individual overriding  Date/time of override  Reason for override |  |  |
| 2.14 | All patient test results supporting the clinical advisory service must be electronically transferred from the haematology/chemistry LIMS where relevant. | Use evidence obtained from 2.13 testing |  |  |
| 2.15 | The clinical advisory service must also support test results obtained from equipment outside of the LIMS control, including point of care devices such as:   * Haemoglobin monitors * Coagulation monitors * Thromboelastography devices (TEG/ROTEM) | Use 2.13 test patients with results:  Manually input for Hb (Hemocue)  Obtained from Beaker for INR (CoaguChek)  Interfaced to EPR (TEG) |  |  |
| 2.16 | The system must support the entry of clinical special requirements (e.g. irradiated, washed, HLA matched or CMV negative) and flag these to the laboratory via the LIMS interface.  This must include guidance on when such special requirements are needed, for example hyperlinks to external guidance documents | Confirm that special requirement flags can be added to patient record based on:  Allogeneic haemopotietic stem cell transplant recipients from the time of conditioning therapy, continues while the patient is receiving GvHD prophylaxis. If chronic GvHD present or taking immunosuppressants irradiated components required indefinitely  Allogeneic bone marrow or stem cell donors, 7 days prior to and during the harvest  Autologous stem cell recipients from conditioning therapy until 3 months post-transplant (6 months if total body irradiation is used)  Patients undergoing bone marrow or peripheral blood stem cell harvesting for future autologous reinfusion during and for 7 days before harvest  All donations from HLA matched donors or first or second degree relatives (even if the recipient is immunocompetent)  Severe T-Lymphocyte immunodeficiency syndromes  Patients with Hodgkin lymphoma  Patients treated with purine analogue drugs  (Fludarabine, Cladribine, Deoxycoformicin, Bendamustine and Clofarabine)  Patients treated with Alemtuzumab and/or Rabbit Anti Thymocyte Globulin (ATG)  Intra-uterine transfusions (IUT)  Exchange transfusion in neonates  Top-up transfusion in neonates (if there has been an IUT, exchange transfusion or if the donor is a first or second degree relative) until 6 months after the expected delivery date.  Platelets transfused in utero to treat alloimmune thrombocytopaenia and top up platelet transfusions until 6 months after the expected date of delivery  Granulocyte transfusion  CMV negative:  Intrauterine transfusions  Exchange transfusion  Neonates up to 28 days post expected date of delivery  Pregnant women for planned non-urgent transfusions  Granulocytes components for CMV seronegative patients |  |  |
| 2.17 | The system must include appropriate rules to determine whether a blood sample is required based on information supplied from the LIMS | EPR displays sample valid if:  Most recent sample has been taken within last 72 hours and has been resulted with blood group and antibody screen  Most recent sample has been taken within last 72 hours and has been resulted with blood group and antibody screen and there is a subsequent sample “in process”  Most recent sample has been taken within last 72 hours and has been resulted with blood group and antibody screen and there is a subsequent sample “not tested”  Most recent sample has been taken within last 72 hours and has negative antibody screen  Most recent sample has been taken within last 72 hours and has positive antibody screen  EPR displays – no valid sample if:  Most recent sample is >72 hours old  Sample is “in process” in the laboratory – EPR clear that another sample is not required  Most recent sample <72 hours old but has no blood group and antibody screen (not tested) –  Duplicate sample  Underfilled sample  Mislabelled sample |  |  |
| 2.18 | The system must include alerts in situations where a sample is NOT required or is already in the laboratory but action by the laboratory is needed (e.g. issue of components) | EPR test request indicates sample NOT required:  Group and save sample tested <72 hours with blood group and antibody screen  Group and save sample in lab “in process”  EPR component/product request indicates sample NOT required:  Historic blood group and antibody screen on record (no time limit)  Group and save sample in lab “in process” |  |  |
| 2.19 | The system must provide a process for monitoring of the electronic interfaces between the IT systems required to support the electronic request management process (Order Comms/PAS/LIMS) with user alerts in the event of interface failure | Demonstrate access to interfaces:  LIMS  TEG  BEAKER  Note – this is more relevant to LIMS for laboratory but needs to be demonstrated that IMT can see interfaces and can take action in the event of interface failure |  |  |
| 2.20 | The system must provide automatic detection of any discrepancy of demographic data between the LIMS, PAS and Order Comms systems with appropriate user alerts | Demonstration that EPR identifies discrepancies in the following data fields:  Surname  Forename  DOB  Hospital Number  NHS number  Blood group  Special requirement (irradiated and CMV negative) |  |  |
| 2.21 | The system must provide a warning to the requestor if a request is rejected and the reason why, override with full audit trail and meaningful reason input | Demonstrate with all reasons for sample rejection:  Sample mislabelled/unlabelled  Sample insufficient  Duplicate sample not required |  |  |
| 2.22 | The system must provide a mechanism to monitor work progress and to alert users if predefined sample receipt or process times are not met. | Demonstrate that EPR tracks sample progress on patient home screen:  Sample collection time  Sample receipt in lab  Anticipated sample completion time based on TAT  Alert if sample exceeds TAT |  |  |
| 2.23 | If Order Comms is used manual requests should be kept to a minimum but will have to be used:  ● during roll out of a new system;  ● during periods of system unavailability.  Mechanisms for manual requesting will therefore need to be in place. It is important to develop robust processes for manual data entry to mitigate risk at each stage of the process. Care must be taken to ensure any patient special requirements are captured. Appropriate controls will need to be in place to manage the subsequent update of the relevant IT systems  Please specify how this will be achieved | Demonstration of process in event of EPR downtime:  Create a manual request and process through LIMS  Send results across interface  Demonstrate that results appear in patient record when EPR up  Scan paper request form into EPR  Demonstrate that sample taken and processed during downtime is clear in EPR audit trail |  |  |
| 2.24 | The supplier must detail the contingency plans for system down-time including the process for dealing with outstanding requests when the system is back on-line | Evidence of manual request forms for:  Group and save  Blood components  Batch products |  |  |
| 2.25 | The system must include a summary of blood component/product transfusions during the admission period in the form of a discharge summary.  This report should include number and type of component/product transfused  The system must be capable for electronic transmission of the summary report to the patient primary care provider | Review discharge summaries for 10 patients with transfusion samples and blood component/batch transfusions, including at least:  Group and save  Kleihauer  DAT  Red cell transfusion  FFP transfusion  Platelet transfusion  Cryo transfusion  Octaplas transfusion  Anti-D  Albumin  IVIg  Anti-tetanus  Factor concentrate  Praxbind |  |  |
|  |  |  |  |  |
| 3 | Sample Collection (Order Comms) |  |  |  |
| 3.1 | The sample collection process must conform with the Guideline for the  Administration of Blood Components (BCSH 2017)  Please specify details on how assurance that the sample is labelled at the patient side is achieved | Demonstration that EPR sample taking process for all transfusion samples in enabled via Electronic blood management :  Sample taking in EPR  Access to Electronic blood management  Scan in authorised user – access to sample taking enabled  Scan in unauthorised user – access to sample taking denied  EPR/Beaker sample taking denied for transfusion related sampling  Take sample using Electronic blood management  Scan patient ID band – sample taking enabled  Scan other patient ID (linear barcode) – sample taking denied  Demonstrate ID band scanning required if process takes >30 seconds  Demonstrate full audit trail – EPR and Electronic blood management related |  |  |
| 3.2 | Each sample must be uniquely identified preferably including a unique barcoded sample identification number that can be used throughout the laboratory process thus eliminating the need for any re-labelling. If sample labels are printed by the electronic request management system the following must apply:  ● verification of the match between the patient and the computer record and printing of the sample label must be performed at the bedside at the time of phlebotomy (please detail how this is achieved);  ● date and time of collection of the sample must be recorded on the label.  • Details of the person responsible for taking the sample | How will the unique sample number be generated? |  |  |
| 3.3 | The system must include a record of confirmation that the individual taking the sample has positively identified the patient and generated the label at the time of the phlebotomy event | Demonstration that this is achieved via Electronic blood management for 10 patients  Demonstrate that users cannot collect transfusion samples using EPR/Beaker pathway |  |  |
| 3.4 | The system must include a clear warning of the dangers associated with wrong blood in tube events | Demonstration that EPR has warning at transfusion sample taking regarding wrong blood in tube and ABO incompatible transfusion – prior to accessing Electronic blood management |  |  |
| 3.5 | The system must include a process to prevent the production or more than one label per sample, unless two samples are required (eg for group and save plus kleihauer requests) | How will EPR do this? |  |  |
| 3.6 | The system must support a two sample policy:   * Include an alert to the requestor if a second sample is required prior to release of red cells * Prevent multiple sample taking by the same operator at the same time | EPR red cell order process:  EPR allows red cell order if:  1 historic blood group on record (any date) and 1 sample resulted <72 hours (valid results)  1 historic blood group on record and 1 sample in process in lab but not yet resulted  1 historic blood group on record and 1 sample collected but not yet receipted in lab  EPR does not allow red cell order if:  1 historic blood group on record only  EPR allow override in emergency situations for above if:  Second sample has been collected and in transit to lab  Second sample is in process in lab awaiting results  Single sample has been resulted (valid results) and is <72 hours old |  |  |
| 3.7 | The system must support a process for communication to the requestor of samples that have been rejected, including the reason for rejection | How does EPR do this?  Alert on patient home page? |  |  |
| 3.8 | The system must include advice on the sample type required, based on the test requested and including:   * Volume * Anticoagulant, if required | Demonstration of advice including:  6ml EDTA sample for group and save  2.7ml EDTA for kleihauer  2.7ml EDTA for patient <16 years old  1.3ml EDTA for patient 12 months old  Demonstration of information regarding labelling of sample on the EPR sample collect page:  Sample must be labelled using Electronic blood management  In event of Electronic blood management downtime sample must be hand written with following PID:  Surname, forename, DoB and hosp/NHS number  Demonstration that, in event of Electronic blood management downtime EPR forces user to add comment that system down  Full audit trail shows sample handwritten and reason, user, date/time  No drop down boxes – this must be a difficult process to enforce good practice using Electronic blood management |  |  |
|  |  |  |  |  |
| 4 | Requesting red cells |  |  |  |
| 4.1 | The system must support appropriate requesting of red cells in accordance with current BCSH guidelines  The system must be user configurable to enable support of any changes to appropriate use of red cells, or local adaptations |  |  |  |
| 4.2 | The system must provide an alert to users if requesting is outside the triggers set for appropriate requesting, an override with full audit trail must be included within the system | Demonstration using:  Single unit order with Hb>100g/L  2 unit order with Hb >90g/L  2 unit order with Hb>80 g/L  2 unit order for patient with weight <50kg  Demonstration of full audit trail: date/time, user, reason |  |  |
| 4.3 | The system for requesting red cell must alert the user if there is no valid sample available in the laboratory  In this case the system must generate a request for a sample to be taken | Demonstration that red cell order cannot be completed if no valid sample:  EPR creates sample taking order  EPR red cell order can only be completed after sample taking order is generated |  |  |
| 4.4 | The system must include all indications for red cell, as documented in the BCSH guidelines and National Blood Transfusion Committee indication codes  The system must be user configurable to include other indication codes as required | Set up scripts using flow charts  Generate new codes and test, if necessary |  |  |
| 4.5 | The request indication codes must be linked to user configurable haemoglobin triggers where relevant, in a request for transfusion for a non-bleeding patient  The system must alert the user if the haemoglobin is above the set trigger  An override system must be in place, this must include documentation of a reason for override and full audit trail | Set up scripts using flow charts |  |  |
| 4.6 | The red cell request indication codes must link to the MCV result and provide guidance on alternatives to transfusion based on triggers for this parameter  For example, suggest iron treatment if MCV < lower limit of normal, suggest B12/folate treatment if MCV > above upper limit of normal | Demonstrate that red cell order generates advice on iron treatment if MCV <X  Demonstrate that red cell order does not generate advice on iron treatment if MCV between X and X  Demonstrate that red cell order generates advice on B12/folate treatment if MCV >X |  |  |
| 4.7 | The system must only accept FBC parameter triggers (Hb, MCH) from an FBC sample taken in the previous 24 hours | Demonstrate that system does not use results for Hb and MCV if:  Sample was taken more than 24 hours previously  Demonstrate that system does use results for Hb and MCV if:  Sample was taken less than 24 hours previously  Demonstrate that system generates advice to take FBC sample if historic sample >24 hours old  EPR generates FBC request  Do we need it to generate haematinic test request? |  |  |
| 4.8 | The system for requesting red cells for non-bleeding patients must alert the user if there is no valid FBC sample available in the laboratory within the previous 24 hours  In this case the system must generate a request for a sample to be taken  An override system must be in place, this must include documentation of a reason for override and full audit trail | Demonstrate that system does not use results for Hb if:  Sample was taken more than 24 hours previously  Demonstrate that system does use results for Hb if:  Sample was taken less than 24 hours previously  Demonstrate that system generates advice to take FBC sample if historic sample >24 hours old  EPR generates FBC request  Demonstrate that above process is generated for non-bleeding patient  Demonstrate that above process is not generated for bleeding/major haemorrhage/trauma code red patient |  |  |
| 4.9 | The system must support weight-adjusted red cell dosing to guide the appropriate number of units required for all paediatric and neonatal patients | Demonstration that EPR prescribes volumes in mls for:  Red cells  FFP  Octaplas  Cryo  When:  Patient is <16 years old  Patient is <50kg weight |  |  |
| 4.10 | The system must interrogate the LIMS for an extended phenotype (Rh/K) result when a request for group and save or red cells is made for a patient with an underlying diagnosis of haematological malignancy, renal insufficiency or oncology (user definable criteria)  If no results are found the system must automatically add a request for extended phenotype | Demonstration that EPR creates PHENO request:  G&S  Red cell order  When patient is:  Haematology  Renal  Oncology  Paediatric  Demonstration that EPR does not creates PHENO request for above patient type when:  Historic pheno on file with valid results |  |  |
| 4.11 | The system must support remote allocation of red cells from designated blood fridges, with no laboratory involvement, and in accordance with BCSH and MHRA guidelines for electronic issue  This may include an interface with the Electronic blood management system to provide this capability  Please detail how this is achieved | Demonstration that EPR red cell order will proceed directly to Electronic blood management enquiry and show remote allocation red cell availability for eligible patient:  Red cell order for prescription  Red cell order for standby (no prescription)  If above criteria are met EPR does not generate red cell order to lab  If above criteria not me EPR generates red cell order to lab  If red cell prescribed – EPR generates pick-up slip  If red cells not prescribed – EPR does not generate pick-up slip |  |  |
| 4.12 | There must a simple and fast process for requesting red cells for patients with active bleeding  This must include an escalation process to alert laboratory staff to the request  The request must include an indication of the urgency of the requirement (eg red cells required within 20 minutes, within 50 minutes) | Demonstrate EPR pathway for:  Emergency cross match – red cells only:  Reason for request (national indication code extracted from EPR admission record  Number of units required – maximum of 4 at single request  Time required – in minutes (minimum 20)  EPR extracts sample validity:  Valid sample:  Interrogates Electronic blood management for remote allocation units  Remote allocation available – EPR generates pick-up slip  No remote allocation – lab order generated  EPR message – user to phone lab and discuss request  No valid sample:  EPR generates sample taking request  Red cell order completed  EPR message – user to phone lab and discuss request  EPR generates red cell prescription  Major Haemorrhage:  Reason for request (national indication code extracted from EPR admission record/current record  Order generated for 4 red cells and 2 FFP (pack 1)  Time required – in minutes (minimum 20)  EPR extracts sample validity:  Valid sample:  Interrogates Electronic blood management for remote allocation units  Remote allocation available – EPR generates pick-up slip  No remote allocation – lab order generated  EPR message – user to phone lab and discuss request  No valid sample:  EPR generates sample taking request  EPR generates red cell and FFP prescription  Major Haemorrhage request generated within 4 hours of first request  Order generated for 4 red cells and 4 FFP (pack 2)  Time required – in minutes (minimum 20)  EPR extracts sample validity:  Valid sample:  Interrogates Electronic blood management for remote allocation units  Remote allocation available – EPR generates pick-up slip  No remote allocation – lab order generated  EPR message – user to phone lab and discuss request  No valid sample:  EPR generates sample taking request  EPR generates red cell and FFP prescription  Major Haemorrhage request – third request in less than 8 hours:  Order generated for 4 red cells and 4 FFP and 1 platelet (pack 3)  Time required – in minutes (minimum 20)  EPR extracts sample validity:  Valid sample:  Interrogates Electronic blood management for remote allocation units  Remote allocation available – EPR generates pick-up slip  No remote allocation – lab order generated  EPR message – user to phone lab and discuss request  No valid sample:  EPR generates sample taking request  EPR generates red cell, platelet and FFP prescription  Major haemorrhage event – EPR allows order generation of additional products in pack 1 or2:  PCC  Cryo  Platelets  Fibrinogen concentrate  Order requires reason from drop down:  PCC = on warfarin INR>2  Cryo = TEG advice  Thrombolytic therapy  Inherited hypofibrinogenamia (fib conc not available)  Platelets = TEG advice  Platelet count <50  Platelet count <100 critical site  Primary immune thrombocytopaenia  Patient on anti-platelet therapy  Inherited platelet disorders (directed by haematology consultant)  Fibrinogen concentrate = obstetric bleed fib <2  All reason have option for “other” with free text entry  All additional product orders capture full audit trail (user, reason, date/time) and allow report generation for monitoring  Trauma code red:  EPR generates order for 2 group O units and 4 FFP in a transport box  Reason – major trauma only  Does not allow generation if patient admission reason is not trauma related  Does not allow generation from any location other than ED  Order can only be generated by ED consultant  Order cannot be generated by:  Doctor other than consultant  Nurse  ODP  HCA  Porter  Order may be generated in absence of full patient identification but must include:  Gender  Approximate patient age  Requirement to contact laboratory by phone  Does not allow generation of orders for other blood components:  Test using cryo, platelets, fib conc, PCC |  |  |
|  |  |  |  |  |
| 5 | Requesting FFP and Cryoprecipitate |  |  |  |
| 5.1 | The system must support appropriate requesting of FFP and Cryoprecipitate in accordance with current BCSH guidelines  The system must be user configurable to enable support of any changes to appropriate use of FFP/cryoprecipitate, or local adaptations | Order for FFP can be generated when:  Reason = major haemorrhage pack 1, 2 or 3    Bleeding with INR>1.5  Pre-procedure INR>1.5  DIC with INR>1.5  Liver disease and INR>2 and pre-procedure  TTP/plasma exchange  Replacement of single coagulation factor  EPR demonstrated to extract INR from Beaker to support FFP request  Order for FFP cannot be generated when:  INR<1.5 and bleeding  INR<1.5 and pre-procedure  INR<1.5 and DIC  INR<2 and liver disease and pre-procedure  Override for above excursions available with full audit trail (user, reason, date/time)  FFP order can be generated by medical staff  FFP order cannot be generated by nursing staff, HCA, ODP or porting staff  Cryo order can be generated when:  Bleeding and fibrinogen <1.5 g/L (non obstetric patient)  Bleeding and fibrinogen <2 g/L (obstetric patient)  Fibrinogen <1g/L and pre-procedure  Bleeding associated with thrombolytic therapy  Inherited hypofibrinogeneaemia and fibrinogen concentrate not available  Cryo order can be generated by medical staff  Cryo order cannot be generated by nursing staff, HCA, ODP or porting staff  Order for FFP generates prescription  Order for Cryo generates prescription  Electronic blood management enquiry can be accessed through patient record to view product availability  Prescription ready and product ready – Electronic blood management pick-up slip generated  FFP/Cryo can be administered via EPR-Electronic blood management  If within trigger value and blood group available– prescription generated  If within trigger but no blood group available – EPR generates prescription and order for group and save |  |  |
| 5.2 | The system must include all indications for FFP/cryoprecipitate, as documented in the BCSH guidelines and National Blood Transfusion Committee indication codes  The system must be user configurable to include other indication codes as required | Demonstration that additional indication codes can be added to EPR by Hospital Transfusion Team members only:  Authorised user can add indication codes  Unauthorised users cannot add additional codes  Full audit trail of addition of codes retained by EPR (user, reason, date/time) |  |  |
| 5.3 | The system must provide an alert to users if requesting is outside the triggers set for appropriate requesting, an override with full audit trail and clinical justification must be included within the system | Demonstration that EPR can extract INR and fibrinogen information from Beaker to advice on request  Test using FFP request for bleeding and INR <1.5  Test for FFP request for liver disease pre-procedure and INR<2  Test using Cryo request for obstetric patient with fib >2  Test using Cryo request for non- obstetric patient with fib >1.5  Demonstration that request outside set limits result in alert to user |  |  |
| 5.4 | The request indication codes must be linked to a user configurable coagulation parameter triggers (prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen)  The system must alert the user if the relevant coagulation parameter is above the set trigger  An override system must be in place, this must include documentation of a clinical justification for override and full audit trail | Test above linked to INR and fibrinogen parameters from:  Beaker  Coaguchek devices (via Beaker)  Manual type in from POCT device (with audit trail)  Demonstrate that alert can be overrriden with full audit trail (user, reason, date/time)  EPR can generate reports on overrides to monitor and trend |  |  |
| 5.5 | The FFP/cryoprecipitate request indication codes must link to the relevant coagulation parameter result and provide guidance on alternatives to transfusion based on triggers for this parameter  For example, suggest cryoprecipitate if fibrinogen < 1.5g/L or <2g/L for obstetric bleed, FFP treatment if INR>1.5 | Test advice using following scenarios:  FFP order - INR<1.5 but fib <1.5 g/L = EPR suggests cryo  Cryo order - fib >1.5 but INR>1.5 (non obstetric)  Is this actually going to work??? |  |  |
| 5.6 | The system must only accept coagulation parameter triggers (PT, APTT, fibrinogen) from a coagulation sample taken in the previous 6 hours | This work flow is only for FFP and Cryo orders when NOT major haemorrhage  Test FFP order with INR from sample >6 hours  Test cryo order with fib from sample >6 hours old  Confirm that EPR alerts user and proceeds to COAG order and sample collection process |  |  |
| 5.7 | The system must accept coagulation results from POCT devices (TEG or ROTEM) and provide clinical guidance of FFP/cryoprecipitate based on user configurable algorithms  The results from POCT devices must be input electronically directly from the device, including the identity of the user | Confirm that INR value can be input from POCT – manual with audit trail  Confirm that Cryo order can be generated from manual input of TEG values  Confirmation that TEG values can be input via the TEG interface  Confirmation that TEG order does not have to be placed prior to results (ie EPR will accept unsolicited TEG results) |  |  |
| 5.8 | The system for requesting FFP/Cryoprecipitate must alert the user if there is no valid coagulation sample available in the laboratory within the previous 6 hours  In this case the system must generate a request for a sample to be taken  An override system must be in place, this must include documentation of a reason for override and full audit trail | Tested above  Confirm that COAG order is generated including sample collect  Confirm that FFP/cryo order can only be completed using the override function or the manual POCT function or TEG interface  Confirmation that audit trail of override is retained in EPR  Confirmation that override reports can be generated for monitoring and trend analysis |  |  |
| 5.9 | The system must support weight-adjusted FFP/Cryoprecipitate dosing to guide the appropriate volume (mls) required for all paediatric and neonatal patients | Confirmation that EPR produces prescription for FFP and Cryo based on mls for patients <16 years old  Do we need EPR to do this for patients <50kg as well? |  |  |
|  |  |  |  |  |
| 6 | Requesting platelet concentrates |  |  |  |
| 6.1 | The system must support appropriate requesting of platelet concentrates in accordance with current BCSH guidelines  The system must be user configurable to enable support of any changes to appropriate use of red cells, or local adaptations | EPR generates platelet order based only on following selectable reasons:  Bone marrow failure – plts <10 x 109  Sepsis/haemostatic abnormality plts <20 x 109  Central venous line insertion plts<20 x 109  Pre lumbar puncture/spinal anaesthesia plts <40 x 109  Pre liver biopsy/major surgery plts <50 x 109  Epidural anaesthesia plts <80 x 109  Pre critical site surgery plts <100 x 109  Major haemorrhage plts<50 x 109  Critical site bleeding plts <100 x 109  DIC pre procedure or bleeding  Primary immune thrombocytopaenia (emergency pre-procedure/severe bleeding)  Critical bleeding on anti-platelet agent  Inherited platelet disorders directed by haematology consultant  EPR pulls plts count from Beaker  EPR pulls blood group from BT LIMS  If within trigger value and blood group available– prescription generated  If within trigger but no blood group available – EPR generates prescription and order for group and save |  |  |
| 6.2 | The system must provide an alert to users if requesting is outside the triggers set for appropriate requesting, an override with full audit trail must be included within the system including the clinical justification for the request | Test using values outside triggers:  Bone marrow failure – plts >10 x 109  Sepsis/haemostatic abnormality plts >20 x 109  Central venous line insertion plts>20 x 109  Pre lumbar puncture/spinal anaesthesia plts >40 x 109  Pre liver biopsy/major surgery plts >50 x 109  Epidural anaesthesia plts >80 x 109  Pre critical site surgery plts >100 x 109  Major haemorrhage plts>50 x 109  Critical site bleeding plts >100 x 109  Confirm that EPR alerts users that request not valid  Override available with full audit trail (user, reason, date/time)  Report function available for monitoring and trend analysis |  |  |
| 6.3 | The request indication codes must be linked to a user configurable coagulation parameter triggers (platelet count)  The system must alert the user if the relevant platelet count parameter is above the set trigger  An override system must be in place, this must include documentation of a clinical justification for override and full audit trail | Confirm that platelet count can be extracted from Beaker  Confirm alert system  Confirm override system |  |  |
| 6.4 | The platelet concentrate request indication codes must link to the relevant platelet count result and provide guidance on alternatives to transfusion based on triggers for this parameter  For example, suggest platelet concentrate if platelets < 10 x 109/L for reversible bone marrow failure, if platelets 10-20 x 109/L for sepsis/haemostatic abnormality | Confirmation for haematology patients on receipt of platelet count <20 x 109 clinical support advice is available through EPR |  |  |
| 6.5 | The system must only accept platelet count triggers from an FBC sample taken in the previous 24 hours | Confirm that for platelet order EPR interrogates Beaker for platelet count <24 hours to enable generation of order  Confirm that platelet count from FBC >24 hours does not enable generation of platelet order |  |  |
| 6.6 | The system for requesting platelet concentrates must alert the user if there is no valid FBC sample available in the laboratory within the previous 24 hours  In this case the system must generate a request for a sample to be taken  An override system must be in place, this must include documentation of a clinical justification for override and full audit trail | If FBC >24 hours EPR generates FBC order and sample taking process  Platelet order cannot be completed until a valid FBC is processed  Confirm EPR override available with full audit trail (user, reason, date/time)  Confirm report generates for overrides for monitoring and trend analysis |  |  |
| 6.7 | The system must support weight-adjusted platelet concentrate dosing to guide the appropriate volume (mls) required for all paediatric and neonatal patients | Confirmation that platelet order for patients <16 years old is generated in mls (not units) |  |  |
| 6.8 | The system must accept results from POCT devices (TEG or ROTEM) and provide clinical guidance of platelet concentrates based on user configurable algorithms  The system must input results electronically directly from the POCT device, including the identity of the user | Confirmation of interface between TEG and EPR  Confirmation that TEG results can input into the decision support system for platelets  Note: EPR must be able to accept unsolicited TEG results  Platelet orders must be able to be made without TEG results (override)  Confirmation that TEG results transferred to EPR includes the following information:  TEG location/equipment number  Identity of user  Date/time |  |  |
| 6.9 | The system must support a single unit transfusion policy  There must be a fully auditable override system in place to allow request of more than one unit in certain circumstances, the override feature should allow free text entry to justify request | Confirmation that EPR supports order for single platelet concentrate only  Confirmation that EPR accepts order for more than 1 platelet concentrate only with override and audit trail:  User  Reason for override  Date/Time  EPR generates report for all override for platelet orders for monitoring and trend analysis |  |  |
|  |  |  |  |  |
| 7 | Requesting anti-D |  |  |  |
| 7.1 | The system must support requests for anti-D for potentially sensitising events and for routine antenatal anti-D prophylaxis (RAADP) | Confirmation that order for anti-D can be generated in EPR  Confirmation that order generated in EPR appears in the LIMS |  |  |
| 7.2 | The system must include a confirmation step during the request for anti-D to ensure that this is only requested for RhD negative women  The system must interrogate the LIMS to obtain the RhD type of the patient | Confirmation that EPR interrogates LIMS for RhD result:  Historic RhD type (any date)  RhD negative result allows continuation of order  RhD positive results does not allow continuation of order  Group and save sample in lab in process does not allow continuation of order |  |  |
| 7.3 | If there is no RhD type on the LIMS for the patient the system must initiate a request for a sample and test for blood group | No group and save does not allow continuation of order but generates request for group and save sample |  |  |
| 7.4 | The system must interrogate the LIMS to identify if a cffDNA test result is available for the current pregnancy and include a warning, with auditable override, if the result is RhD negative and anti-D is not recommended  There must be a fully auditable override system in place to allow request of anti-D if the cffDNA result is RhD negative, the override feature should allow free text entry to justify request | Confirmation that EPR contains field to note that patient has consented to cffDNA for RhD testing  Confirmation that if patient has consented EPR does generate order for cffDNA sample collection and test request is received in LIMS  Confirmation that EPR contains field to note that patient has not consented for cffDNA for RhD testing  Confirmation that if patient has not consented EPR does not generate order for cffDNA sample collection and test  Test using following scenarios for orders up to 12 weeks:  Order for anti-D – reason selected from the following:   * therapeutic termination of pregnancy, whether by surgical or medical methods, to confirmed Rh D negative women who are not known to be already sensitised to D (RCOG, 2002). * bleeding is heavy or repeated or where there is associated abdominal pain, particularly if these events occur as gestation approaches 12 weeks.   Test using following scenarios for orders 12- 20 weeks:  Order for anti-D – reason selected from the following:   * Amniocentesis * Cordocentesis * Other in-utero therapeutic intervention/surgery (e.g. intrauterine, shunting) * Ante partum haemorrhage * Chorionic villus sampling * Ectopic pregnancy * External cephalic version * Fall/abdominal trauma * Intrauterine death * Miscarriage * Termination of pregnancy * Abdominal pain with reasonable suspicion of abruption   Test using following scenarios for anti-D ordered post 20 weeks, including RAADP:  Order for anti-D – patient has RhD negative result on record – cffDNA for current pregnancy is RhD negative = order cannot be completed  EPR displays warning that cffDNA for current pregnancy is negative, anti-D not recommended  Above scenario has override with reason (free text) and audit trail (user, reason, date/time)  Order for anti-D – patient has RhD negative result on record – cffDNA for current pregnancy is RhD positive = order can be completed  Order for anti-D – patient has RhD negative result on record – cffDNA for current pregnancy is not available (in process) = order can be completed  Order for anti-D – patient has RhD negative result on record – cffDNA for current pregnancy is not determined = order can be completed  Order for anti-D – patient has RhD negative result on record – cffDNA for current pregnancy is not available but cffDNA result available from previous pregnancy = order can be completed  Order for anti-D – patient has RhD negative result on record – cffDNA for current pregnancy is not available but cffDNA result available from previous pregnancy is RhD negative= order can be completed |  |  |
| 7.5 | The system must include a selectable list of all reasons for anti-D requirement, including RAADP and all potentially sensitising events.  The list must be user configurable and allow inclusion of newly recognised potentially sensitising events | Confirmation that list includes:   * therapeutic termination of pregnancy, whether by surgical or medical methods, to confirmed Rh D negative women who are not known to be already sensitised to D (RCOG, 2002). * bleeding is heavy or repeated or where there is associated abdominal pain, particularly if these events occur as gestation approaches 12 weeks. * Amniocentesis * Cordocentesis * Other in-utero therapeutic intervention/surgery (e.g. intrauterine, shunting) * Ante partum haemorrhage * Chorionic villus sampling * Ectopic pregnancy * External cephalic version * Fall/abdominal trauma * Intrauterine death * Miscarriage * Termination of pregnancy * Abdominal pain with reasonable suspicion of abruption * RAADP |  |  |
| 7.6 | The system must alert the requestor to include a FMH test according to user configurable rules based on reason for request and gestational age | Test using following reasons for request for anti-D orders post 20 weeks:   * Amniocentesis * Cordocentesis * Other in-utero therapeutic intervention/surgery (e.g. intrauterine, shunting) * Ante partum haemorrhage * Chorionic villus sampling * Ectopic pregnancy * External cephalic version * Fall/abdominal trauma * Intrauterine death * Miscarriage * Termination of pregnancy * Abdominal pain with reasonable suspicion of abruption   Confirm that above orders generate order for FMH test in EPR and is transferred to LIMS  Confirm that sample collection event is generated in EPR  Confirm that order for RAADP does not generate FMH request |  |  |
| 7.7 | The system must advise the requestor on the minimum dose of anti-D required according to user configurable rules based on reason for request and gestational age | Confirm that EPR offers 500 iu anti-D when following reason selected:   * therapeutic termination of pregnancy, whether by surgical or medical methods, to confirmed Rh D negative women who are not known to be already sensitised to D (RCOG, 2002). * bleeding is heavy or repeated or where there is associated abdominal pain, particularly if these events occur as gestation approaches 12 weeks. * Amniocentesis * Cordocentesis * Other in-utero therapeutic intervention/surgery (e.g. intrauterine, shunting) * Ante partum haemorrhage * Chorionic villus sampling * Ectopic pregnancy * External cephalic version * Fall/abdominal trauma * Intrauterine death * Miscarriage * Termination of pregnancy * Abdominal pain with reasonable suspicion of abruption   Confirm that EPR generates order for 1500iu when RAADP reason selected  Confirm that EPR retains the record of the actual dose administered to the patient when 1500iu is used instead of 500iu in case where 500iu recommended by EPR |  |  |
| 7.8 | The system must include advice on follow-up testing and anti-D requirements following receipt of a positive FMH test result from the LIMS, according to BCSH recommendations | Test with following scenarios:  FMH test results = <4ml bleed:  No comment and no further actions in EPR  FMH>4ml:  Anti-D required and comment states volume of bleed  EPR generates repeat FMH sample and test to be collected 72 hours post anti-D administration  Further action scenarios from repeat test at 72 hours for testing:  No foetal cells present & No free anti-D Give further 500IU dose of anti-D. Request a repeat sample for antibody screening 6 months after the sensitising event.  No foetal cells present & Free anti-D No further anti-D required. . Request a repeat sample for antibody screening 6 months after the sensitising event.  Foetal cells present & No free anti-D Quantify and give appropriate further dose of anti-D.  Repeat FMH assessment and re-test the plasma for presence of free anti-D every 48 hours until there are no remaining foetal cells  Foetal cells present & Free anti-D Quantify and consider giving anti-D appropriate to the packed cell volume of the remaining foetal cells, (Contact an NBS consultant for advice). Repeat FMH assessment in 48 hours |  |  |
| 7.9 | The system must support a process for recording when a patient has declined anti-D, including the reason for refusal | EPR contains field for noting that a patient has declined anti-D:  Field available at FTS booking appointment  Field available at anti-D administration module  Field contains free text entry for reason  EPR generates report on declined anti-D for monitoring and trend analysis |  |  |
| 7.10 | Administration | Confirmation that EPR interfaces to Electronic blood management to allow administration of anti-D  Confirmation that EPR retains administration information for product:  User  Date/time of begin administration  Unique product number  Unique product code |  |  |
| 8 | Requesting IVIg |  |  |  |
| 8.1 | The system must support requests for IVIg in accordance with the national database indication codes (clinical guidelines summary data)  The system must be configurable to include or exclude indication codes, as required  The system must be configurable to enable changes to dosing strategy (eg change of indication from “red –short term” to “blue- short term” | Confirmation that EPR contains fields for all data points in:  Immunoglobulin request form – short term us- Form 1  Immunoglobulin long term – Form 2  Immunomodulation long term – Form 3  Confirmation of inclusion of following indication codes:  Commissioned:  Primary immunodeficiencies – long term use  Thymoma with immunodeficiency – long term use  HSCT in primary immunodeficiency – long term use  Neonatal alloimmune thrombocytopenia  Haemolytic Disease of the Foetus and Newborn – short term use  Immune thrombocytopenia – short term use  Autoimmune haemolytic anaemia – acute episodes  Post transfusion hyperhaemolysis – short term use  Post transfusion purpura – short term use  CIDP – short term to assess responsiveness  Guillain-Barre syndrome – short term  Myasthenia Gravis – short term  Multifocal motor neuropathy – short term to assess responsiveness  Tetanus prone injury  Suspected tetanus case  Non-commissioned:  Specific antibody deficiency – long term use  Secondary antibody deficiency – long term use  Foeto-maternal alloimmune thrombocytopenia  Immune thrombocytopenia – long term use  Acquired red cell aplasia associated with chronic parvovirus B19 infection – short term use  Autoimmune haemolytic anaemia – repeat courses  Coagulation factor inhibitors – short term use  Haemophagocytic syndrome – short term use  CIDP – long term  IgM paraprotein-associates demyelinating neuropathy  Inflammatory myopathies dermatomyositis (DM) polymyositis (PM)  Myasthenia Gravis – long term  Multifocal motor neuropathy – long term  Rassmussen’s encephalitis  Stiff person syndrome  Hepatitis A  Measles (immunosuppressed individuals)  Measles (pregnant women and infants)  Polio  Varicella zoster  Confirmation that for non-commissioned reasons EPR alerts the user to requirement to complete immunoglobulin request form and does not complete IVIg order process |  |  |
| 8.2 | The system must link to external systems, if required, for NHS England high cost drug ordering (eg BlueTeq) | Confirmation that EPR can link to national IVIg database and transmit required data  Note: acceptable for EPR not to have this functionality at go-live |  |  |
| 8.3 | The system must create an alert to the requestor if the indication is in the Grey or Black category of the national indication codes  The alert must include instructions of procedures to take if IVIg is indicated for that particular case | Confirmation that for non-commissioned reasons EPR alerts the user to requirement to complete immunoglobulin request form and does not complete IVIg order process  Request form information included in EPR  User completes request form – mandatory questions  Once complete the request form can be emailed via EPR to the HTT generic email account as a pdf  Once complete the request from can be printed  Confirmation that a completed request form can be accessed and details amended  Confirmation that EPR retains a full audit trail of any amendments made, including user, reason for amendment, date/time  EPR generates reports of amendments to IVIg request forms for monitoring and trend analysis |  |  |
| 8.4 | The system must include a dosing calculator based on ideal body weight (IBW)dosing, in accordance with local rules  The algorithm for IBW dosing must include exclusion rules based on age and height, these must be user configurable | Confirmation that IBW dosing calculator can be accessed through EPR  Confirmation that completed IBW can be emailed to HTT generic email address as pdf  Confirmation that IBW dosing information is retained in EPR in the patient record for that episode  Confirmation that EPR enforces IBW dosing calculator completion for all new IVIg requests  Confirmation that EPR enforces IBW dosing calculator completion every 12 months for long term patients from registration  Note: no requirement to validate IBW calculator if current calculator used  Confirmation of override facility for dosing with full audit trail – user, reason for override, date/time  EPR generates reports of IBW calculator over rides for monitoring and trend analysis |  |  |
| 8.5 | The system must support collection of all data elements required by the national IVIg database (MSDAS) for initial request for IVIg  The system must include a link to the MSDAS for electronic transfer of required information for all red and blue category patients | Confirmation that every data field required for IVIg forms is mandatory:  Registration form  Form 1  Form 2  Form 3  Follow up form  Note: acceptable if this link is not in place at EPR go-live, unclear if national database will accept electronic transfer of data |  |  |
| 8.6 | The system must automatically assign a dosing regimen depending on the indication for the request (eg 1g/kg for ITP) | Confirmation that dosing regime clear for clinical indications:  Replacement therapy = 0.4 g/kg  Immunomodulatory therapy = 2 g/kg  ITP = 1 g/kg |  |  |
| 8.7 | The system must include a process for approval of the request from a designated IVIg panel member | Note: this process is not required  Immunoglobulin forms 1, 2 and 3 are for IPA review and approval  Confirmation that EPR does not allow IVIg order to complete if IAP approval is required (non-commissioned clinical indications) |  |  |
| 8.8 | The system must create a follow up report within a time period based on the treatment protocol (eg 12 months for a long term treatment request)  The follow up report must contain all data sets required by MSDAS  The system must be able to link to MSDAS to transfer the information included in the follow up report | Confirmation that for patients on long term IVIG an annual review date can be set in EPR  Confirmation that at annual review date a reminder is sent from EPR to the consultant via email  Confirmation that for patients on short term IVIG a 3 month review date can be set in EPR  Confirmation that at annual review date a reminder is sent from EPR to the consultant via email  Confirmation that at 3 month review date a reminder is sent from EPR to the consultant via email  Confirmation that all follow up data item fields are included in EPR and are mandatory  Confirmation that clinical efficacy is included in the data item fields  Confirmation that further IVIg orders cannot be made until the follow up review is completed  Confirmation that completed follow up form can be emailed from EPR to HTT generic email  Note: no requirement for this to be validated for go-live, no confirmation that database can accept electronic information |  |  |
| 8.9 | The system must be capable of receiving information from the LIMS regarding release of IVIg, including the following as a minimum:   * Product unique identification number * Product expiry date * Date/time of laboratory issue * Location of anti-D * Dereservation date of product | Confirmation that information relating to IVIg issued via the LIMS is received in EPR:   * Product unique identification number * Product expiry date * Date/time of laboratory issue * Location of anti-D * Dereservation date of product   Confirmation that EPR can print Electronic blood management pick-up slip  Confirmation that EPR interfaces to Electronic blood management to allow administration of IVIg  Confirmation that EPR retains administration information for product:  User  Date/time of begin administration  Unique product number  Unique product code |  |  |
| 8.10 | The system must provide a link to information regarding the reconstitution and safe administration of the product  This must link to the information relevant to the IVIg type released by the laboratory | Confirmation that EPR has hyperlink to Trust guideline for IVIg administration  Confirmation that EPR contains data fields for patient observations for administration:  Check whether the patient has consented to the infusion and ask whether they have experienced adverse events with previous infusions; discuss with doctor if concerned  Document patient observations: Blood Pressure, Pulse, Temp and respiratory rate as well as weight on chart below  A repeat set of observations are made 15 minutes after the start of the infusion  Confirmation that observations can be recorded on EPR  Confirmation that EPR alerts user if observations are not recorded |  |  |
|  |  |  |  |  |
| 9 | Requesting human albumin solution (HAS) |  |  |  |
| 9.1 | The system must support requests for HAS in accordance with user definable criteria  The system must be configurable to allow addition and/or removal of indication codes, as required | Confirmation that order for HAS can be generated on EPR  Confirmation that HAS order on EPR transfers to LIMS:  5% HAS  20% HAS  Confirmation that EPR contains following clinical indications codes for 20% HAS order:  Ascites  Low albumin  Other – free text  Confirmation that EPR contains following clinical indications codes for 5% HAS order:  Fluid replacement  Plasma exchange  Other – free text |  |  |
| 9.2 | The system must support requests for all available concentrations of HAS (20%, 4.5% and 5%) | Confirmation that EPR supports orders for:  20% HAS  5% HAS  4.5% HAS |  |  |
| 9.3 | Requests for HAS to treat low albumin levels must link to the albumin result from the LIMS system from a blood sample taken within 24 hours  An alert system must be in place to inform the requestor in cases where the albumin result is outside set criteria for HAS treatment  There must be a fully auditable override system in place if HAS is required outside of the set criteria | Confirmation that for 20%HAS order for reason = low albumin:  EPR interrogates Beaker for albumin level  If alb<???? – order allowed and completes  If alb>????? – order not allowed – EPR alerts user that request is not within guidelines  Override facility available with full audit trail ( user, reason, date/time)  EPR generates reports for albumin override for monitoring and trend analysis |  |  |
| 9.4 | The system must be capable of receiving information from the LIMS regarding release of HAS, including the following as a minimum:   * Product unique identification number * Product expiry date * Date/time of laboratory issue * Location of product   Dereservation date of product | Confirmation that once order completed in LIMS EPR receives and retains information on HAS:   * Product unique identification number * Product expiry date * Date/time of laboratory issue * Location of product * Dereservation date of product * Product concentration |  |  |
| 9.5 | Administration | Confirmation that EPR can print Electronic blood management pick-up slip  Confirmation that EPR interfaces to Electronic blood management to allow administration of albumin  Confirmation that EPR retains administration information for product:  User  Date/time of begin administration  Unique product number  Unique product code  Product concentration |  |  |
|  |  |  |  |  |
| 10 | Requesting factor concentrates |  |  |  |
| 10.1 | The system must support requests for factor concentrates in accordance with user definable criteria | Confirmation that EPR can generate orders for specific factor concentrates:  Factor VIII  Factor IX  Confirmation that order includes reason:  Maintenance dose  Bleeding  Pre-operative  Other – free text |  |  |
| 10.2 | The system must support requests for all available types factor concentrates  The system must support addition of any future factor concentrates that become available | Factor VIII:  Advate  Elocta  Refacto AF  Fanhdi  Factor IX:  Alprolix  Benefix  Von Willebrand’s factor:  FIEBA  Voncento  Wilate |  |  |
| 10.3 | Requests for factor concentrates to treat low specific factor levels must link to the relevant coagulation factor result from the LIMS system from a sample taken within 6 hours  An alert system must be in place to inform the requestor in cases where the factor concentrate request is outside set criteria for treatment  There must be a fully auditable override system in place if factor concentrate is required outside of the set criteria | Confirmation that for factor concentrate order for reason  EPR interrogates Beaker for specific factor level  If F VIII<???? – order allowed and completes  If FVIII>????? – order not allowed – EPR alerts user that request is not within guidelines  If F IX<???? – order allowed and completes  If FIX>????? – order not allowed – EPR alerts user that request is not within guidelines  Override facility available with full audit trail ( user, reason, date/time)  EPR generates reports for albumin override for monitoring and trend analysis |  |  |
| 10.4 | The system must provide a link to information regarding the reconstitution and safe administration of the product | Confirmation that EPR can hyperlink to manufacturer website for product safety sheet:  Advate  Elocta  Refacto AF  Fanhdi  Alprolix  Benefix  FIEBA  Voncento  Wilate |  |  |
|  | The system must be capable of receiving information from the LIMS regarding release of factor concentrates, including the following as a minimum:   * Product unique identification number * Product expiry date * Date/time of laboratory issue * Location of product * Dereservation date of product | Confirmation that once order completed in LIMS EPR receives and retains information on factor concentrate:  • Product unique identification number  • Product expiry date  • Date/time of laboratory issue  • Location of product  • Dereservation date of product  • Product concentration  Confirmation that EPR can print Electronic blood management pick-up slip  Confirmation that EPR interfaces to Electronic blood management to allow administration of factor concentrate  Confirmation that EPR retains administration information for product:  User  Date/time of begin administration  Unique product number  Unique product code  Product concentration |  |  |
|  |  |  |  |  |
| 11 | Requesting prothrombin complex concentrate (PCC) |  |  |  |
| 11.1 | The system must support requests for PCC in accordance with user definable criteria  The set criteria must include requests for the urgent reversal of warfarin and reversal of certain DOACs (user configurable) | Confirmation that EPR can generate order for PCC  Confirmation that order for PCC includes following reasons:  Reversal of warfarin:  Intracranial haemorrhage  Life/limb/sight threatening bleed  Pre-procedure (for procedures required within 8 hours)  Reversal of DOAC:  (Drop down list for DOAC)  Dabigatran – EPR alerts user to Praxbind and does not complete order for PCC  Apixaban  Edoxaban  Rivaroxaban  Other (free test)  Confirmation that EPR order for PCC transfers to PCC request in LIMS |  |  |
| 11.2 | The system must support requests for all available concentrations of PCC (1000iu and 500iu) | Confirmation that all PCC orders in EPR state fixed dose of 1000iu |  |  |
| 11.3 | Requests for PCC to reverse warfarin must link to the INR result from the LIMS system  An alert system must be in place to inform the requestor in cases where the INR result is outside set criteria for PCC treatment (eg <2)  There must be a fully auditable override system in place if PCC is required outside of the set criteria | Confirmation that EPR order for PCC for reversal of warfarin includes INR result:  INR manually input from POCT – including user identity, date/time of test  INR electronically extracted from Beaker – from sample taken within previous 6 hours  Confirmation that, if INR <2 EPR alerts user that order is outside guidelines – contact consultant haematologist – order in EPR is not completed  Confirmation of override facility to complete the order – with full audit trail (user, reason, date/time) |  |  |
| 11.4 | For warfarin reversal the system must include advice relating to use of vitamin K for non-urgent reversal or if the INR is <2 | Confirmation that EPR PCC order contains advice for use of vitamin K:  5-10mg iv  Confirmation that if INR<2 vitamin K is recommended  Does EPR need to proceed to pharmacy order for vitamin K? |  |  |
| 11.5 | For urgent reversal of warfarin, with INR >2, the system must include advice to administer an initial dose of 1000iu and repeat the INR 10 minutes after administration | Confirmation that order for PCC with INR>2 includes advice to use 1000iu and then repeat INR within 10 mins of administration  Confirmation that order is generated for INR test  Confirmation that INR test result can be:  Input manually from POCT – including user, date/time  Input electronically from Beaker from sample taken at least 10 following “begin transfusion” of PCC on Electronic blood management |  |  |
| 11.6 | For urgent reversal of warfarin, with INR >2, the system must include advice to collect emergency PCC from the relevant locations (eg user defined blood fridge locations) | Confirmation that if reason = reversal of warfarin or DOAC for ICH, life/limb/sight threatening bleed – EPR advises user to collect emergency PCC from:  Batch fridge in main theatres  Or  Laboratory |  |  |
| 11.7 | Where POCT has been used to determine the INR result the system must force the user to enter the INR result and the identity of the individual who performed the POCT  Wherever possible the system should interface to POCT devices to allow electronic entry of results | Confirmation that if POCT has been used to obtain INR result EPR retains record of:  User identity  Date/time of test  Note: INR devices may interface directly to EPR via the gemweb lab service – this will need validation |  |  |
| 11.8 | The system must provide a link to information regarding the reconstitution and safe administration of the product | Confirmation that EPR provides hyperlink to:  Manufacturers product guidance  Local guidance for safe reconstitution and administration |  |  |
| 11.9 | Request for PCC for DOAC reversal must include advice on specific reversal agents, where available  If a specific reversal agent is available the system must then link to the request process for the relevant reversal agent | Confirmation that EPR redirects to procedure for ordering Praxbind if reversal of DOAC dabigatran is selected  Confirmation that additional specific reversal agents can be added to the system as they become available |  |  |
| 11.10 | The system must be capable of receiving information from the LIMS regarding release of PCC, including the following as a minimum:   * Product unique identification number * Product expiry date * Date/time of laboratory issue * Location of product * Dereservation date of product | Confirmation that once order completed in LIMS EPR receives and retains information on PCC:  • Product unique identification number  • Product expiry date  • Date/time of laboratory issue  • Location of product  • Dereservation date of product  • Product concentration  Confirmation that EPR can print Electronic blood management pick-up slip  Confirmation that EPR interfaces to Electronic blood management to allow administration of factor concentrate  Confirmation that EPR retains administration information for product:  User  Date/time of begin administration  Unique product number  Unique product code  Product concentration |  |  |
|  | Reversal of anticoagulant guidelines | EPR needs to include the new reversal of anticoagulation protocol and flow charts – is this being picked up by transfusion or the surgical teams |  |  |
|  |  |  |  |  |
| 12 | Requesting anti-tetanus |  |  |  |
| 12.1 | The system must support request for anti-tetanus | Confirmation that EPR can generate order for anti-tetanus  Confirmation that order for anti-tetanus generated in EPR is received in the LIMS |  |  |
| 12.2 | The system must support entry of the reason for request, including set user definable criteria and free text entry  The system must be configurable to allow addition and/or removal of reasons for request | Not sure if this is required - maybe just free text or can be extracted from the ED admission details |  |  |
| 12.3 | There must be a fully auditable override system in place if anti-tetanus is required outside of the set criteria, including clinical justification for override | Not sure if this is required - maybe just free text or can be extracted from the ED admission details |  |  |
| 13 | The system must provide a link to information regarding the safe administration of the product | Confirmation that EPR provides hyperlink to:  Manufacturers product guidance |  |  |
| 13.1 | The system must be capable of receiving information from the LIMS regarding release of anti-tetanus, including the following as a minimum:   * Product unique identification number * Product expiry date * Date/time of laboratory issue * Location of product * Dereservation date of product | Confirmation that once order completed in LIMS EPR receives and retains information on anti-tetanus:  • Product unique identification number  • Product expiry date  • Date/time of laboratory issue  • Location of product  • Dereservation date of product  • Product concentration  Confirmation that EPR can print Electronic blood management pick-up slip  Confirmation that EPR interfaces to Electronic blood management to allow administration of factor concentrate  Confirmation that EPR retains administration information for product:  User  Date/time of begin administration  Unique product number  Unique product code  Product concentration |  |  |
|  |  |  |  |  |
| 14 | Requesting C1 esterase inhibitor concentrate |  |  |  |
| 14.1 | The system must support request for C1 EIC | Confirmation that EPR can generate order for C1 EIC  Confirmation that order for C1 EIC generated in EPR is received in the LIMS |  |  |
| 14.2 | The system must support entry of the reason for request, including set user definable criteria and free text entry  The system must be configurable to allow addition and/or removal for criteria for request | Confirmation that EPR includes reason for request:  Short-term prophylaxis of hereditary angioedema before dental, medical, or surgical procedures  Acute attack of hereditary angioedema  Confirmation that additional reasons can be added if required |  |  |
| 14.3 | The system must provide a link to information regarding the reconstitution and safe administration of the product | Confirmation that EPR provides hyperlink to:  Manufacturers product guidance |  |  |
| 14.4 | There must be a fully auditable override system in place if C1 EIC is required outside of the set criteria, including clinical justification for override | Confirmation of override facility in the event that clinician wants to complete order in absence of set reasons  Confirmation of full audit trail of override – user, reason, date/time |  |  |
| 14.5 | The system must be capable of receiving information from the LIMS regarding release of C1EIC, including the following as a minimum:   * Product unique identification number * Product expiry date * Date/time of laboratory issue * Location of product   Dereservation date of product | Confirmation that once order completed in LIMS EPR receives and retains information on anti-tetanus:  • Product unique identification number  • Product expiry date  • Date/time of laboratory issue  • Location of product  • Dereservation date of product  • Product concentration  Confirmation that EPR can print Electronic blood management pick-up slip  Confirmation that EPR interfaces to Electronic blood management to allow administration of factor concentrate  Confirmation that EPR retains administration information for product:  User  Date/time of begin administration  Unique product number  Unique product code  Product concentration |  |  |
|  |  |  |  |  |
| 15 | Requesting DOAC reversal agents |  |  |  |
| 15.1 | The system must support request for DOAC reversal agents which includes the type of DOAC (selected from a user definable list)  The system must support addition of other DOAC agents as they become available | Confirmation that EPR can generate order for DOAC reversal agents:  Dabigatran = Praxbind  Confirmation that order DOAC reversal agents generated in EPR is received in the LIMS |  |  |
| 15.2 | The system must support entry of the reason for request, including set user definable criteria and free text entry | Confirmation that reason for use includes:  ICH  Life/limb/sight threatening bleed  Pre-procedure (within 8 hours)  Free text |  |  |
| 15.3 | There must be a fully auditable override system in place if DOAC reversal agent is required outside of the set criteria, including clinical justification for override | Confirmation that override facility in place if order placed outside of set reason (if free text used)  Confirmation of full audit trail including user, reason and date/time |  |  |
| 15.4 | The system must provide a link to information regarding the reconstitution and safe administration of the product | Confirmation that EPR provides hyperlink to:  Manufacturers product guidance |  |  |
| 15.5 | The process for requesting DOAC reversal agents must link with the process for requesting PCC in the event that PCC is the more appropriate product (or vice versa) | This may not be required if PCC procedure leads clinician to Praxbind if dabigatran is selected |  |  |
| 15.6 | The system must provide advice for reversal of DOAC where there is a specific agent available | This may not be required if PCC procedure leads clinician to Praxbind if dabigatran is selected |  |  |
| 15.7 | The system must be capable of receiving information from the LIMS regarding release of DOAC reversal, including the following as a minimum:   * Product unique identification number * Product expiry date * Date/time of laboratory issue * Location of product * Dereservation date of product | Confirmation that once order completed in LIMS EPR receives and retains information on anti-tetanus:  • Product unique identification number  • Product expiry date  • Date/time of laboratory issue  • Location of product  • Dereservation date of product  • Product concentration  Confirmation that EPR can print Electronic blood management pick-up slip  Confirmation that EPR interfaces to Electronic blood management to allow administration of factor concentrate  Confirmation that EPR retains administration information for product:  User  Date/time of begin administration  Unique product number  Unique product code  Product concentration |  |  |
|  |  |  |  |  |
| 16 | Requesting Octaplas |  |  |  |
| 16.1 | The system must support requests for Octaplas in accordance with user definable criteria  The system must be configurable to allow addition and/or removal of criteria for request | Confirmation that EPR can generate order for Octaplas  Confirmation that reasons for use include:  Plasma exchange – reason extracted from EPR from admission details  Other –free text  Confirmation that order generated in EPR transfers to the LIMS |  |  |
| 16.2 | There must be a fully auditable override system in place if Octaplas is required outside of the set criteria, including clinical justification for override | Confirmation that Octaplas can be ordered for “other” reason but this contains free text reason and clear advice that outside guidelines  Audit trail includes user, reason, date/time  Confirmation that EPR generates reports for Octaplas orders outside plasma exchange for monitoring and trend analysis |  |  |
| 16.3 | The system must provide a dose calculation process based on patient weight and reason for request | Confirmation that EPR includes a dose calculation system for Octaplas  12 - 15 mL /kg body weight  Confirmation that volume of Octaplas calculated by EPR is transferred to the LIMS  Confirmation that EPR calculated dose can be overridden by clinician  Confirmation that override has full audit trail – user, reason, date/time |  |  |
| 16.4 | The system must be capable of receiving information from the LIMS regarding release of Octaplas, including the following as a minimum:   * Product unique identification number * Product expiry date * Date/time of laboratory issue * Location of product * Dereservation date of product | Confirmation that once order completed in LIMS EPR receives and retains information on anti-tetanus:  • Product unique identification number  • Product expiry date  • Date/time of laboratory issue  • Location of product  • Dereservation date of product  • Product concentration  Confirmation that EPR can print Electronic blood management pick-up slip  Confirmation that EPR interfaces to Electronic blood management to allow administration of factor concentrate  Confirmation that EPR retains administration information for product:  User  Date/time of begin administration  Unique product number  Unique product code  Product concentration |  |  |
|  |  |  |  |  |
| 17 | Transfusion reactions |  |  |  |
| 17.1 | The system must include a process for recording transfusion reactions in accordance with the BCSH guidelines  The system must include instructions to contact a Consultant Haematologist for advice in the event of a suspected transfusion reaction | Confirmation that EPR contains pathway for transfusion reaction management  Confirmation that EPR mandates entry of patient observations:  Within 1 hour pre-transfusion  15 minutes post begin transfusion  Within 1 hour post transfusion  Confirmation that EPR mandates entry of the following observation values at each observation:   * Respiratory Rate. * Oxygen Saturation. (Whenever possible) * Temperature. * Heart Rate. * Systolic Blood pressure. * Diastolic Blood pressure   Confirmation that EPR allows identification of the following patient features during any transfusion episode:  Chills  Rigors  Tachycardia  Collapse  Flushing  Urticarial  Pain (bone, muscle, chest, abdominal)  Respiratory distress  Nausea  General malaise |  |  |
| 17.2 | The system must alert the user to a potential transfusion reaction according to set criteria (eg if the temperature has risen by >2oC upon entry of the 15 minute observations, or the post transfusion observations) | Confirmation that EPR alerts user to possible transfusion reaction in the event that any of the following are noted in the patient record at 15 minute or post transfusion observations:  temperature has risen by >2oC  Chills  Rigors  Tachycardia  Collapse  Flushing  Urticarial  Pain (bone, muscle, chest, abdominal)  Respiratory distress  Nausea  General malaise  Confirmation that EPR alerts to possible transfusion reactions includes the following instructions:  Suspend transfusion  Rapid clinical assessment  Check patient ID/blood component compatibility label  Visually assess unit  Confirmation that EPR includes data fields to capture the following information:  Evidence of life threatening airway problem = Yes/No  Evidence of life threatening breathing problem = Yes/No  Evidence of life threatening circulatory problem = Yes/No  Evidence of wrong blood given = Yes/No  Evidence of contaminated unit given= Yes/No |  |  |
| 17.3 | The process for recording transfusion reactions must include instructions on actions to be taken and additional laboratory tests, based on the BCSH criteria for investigation of transfusion reactions | Confirmation that EPR instructs user to stop the transfusion if the following are identified:  Evidence of life threatening airway problem = Yes  Evidence of life threatening breathing problem = Yes  Evidence of life threatening circulatory problem = Yes  Evidence of wrong blood given = Yes  Evidence of contaminated unit given= Yes  Confirmation that EPR for above SEVERE reaction instructs:  Call for urgent medical help  Initiate resuscitation  Maintain venous access  Monitor patient (TPR, BP, urinary output)  Contact consultant haematologist  If likely anaphylaxis/severe allergy – follow anaphylaxis policy  If likely bacterial contamination start antibiotic treatment  Use BP, pulse, urine output to guide intravenous saline administration  Inform transfusion laboratory and return units (with administration set) to lab  Submit DATIX incident report  EPR generates order for pathology tests:  Blood cultures (if febrile reaction)  Repeat group and screen and Direct antiglobulin test (if febrile, hypotension, back/loin pain)  Serial mast cell tryptase and IgA levels (if allergic/anaphylaxis)  HLA, HPA or NHA antibody tests (if febrile reaction)  Chest xray, Echo/Pulmonary wedge pressure (if respiratory distress)  Confirmation that EPR instructs user to suspend the transfusion if the following are identified:  Evidence of life threatening airway problem = No  Evidence of life threatening breathing problem = No  Evidence of life threatening circulatory problem = No  Evidence of wrong blood given = No  Evidence of contaminated unit given= No  Confirmation that EPR for above instructs:  Inform medical staff  Contact consultant haematologist  Confirm EPR process for MODERATE reaction:  temperature rise ≥39oC or rise ≥2oC and/or  other symptoms (not pruritis/rash)  EPR instructs user:  Monitor TPR, BP, oxygen stats, urinary output  EPR includes question : are the patient’s symptoms consistent with condition or history? – Yes/No  If No then EPR instructs:  Discontinue transfusion  Return implicated units to transfusion lab  Submit DATIX incident report  EPR generates order for pathology tests:  Blood cultures (if febrile reaction)  Repeat group and screen and Direct antiglobulin test (if febrile, hypotension, back/loin pain)  Serial mast cell tryptase and IgA levels (if allergic/anaphylaxis)  HLA, HPA or NHA antibody tests (if febrile reaction)  Chest xray, Echo/Pulmonary wedge pressure (if respiratory distress)  EPR includes question : are the patient’s symptoms consistent with condition or history? – Yes/No  If Yes then EPR instructs:  Consider continuation of transfusion at slower rate  Consider appropriate symptomatic treatment  Confirm EPR process for MILD reaction:  Isolated temperature rise ≥38oC or rise1-2oC and/or not pruritis/rash only  EPR instructs user:  Continue transfusion  Consider symptomatic treatment  Monitor TPR, BP, oxygen stats, urinary output  If symptoms worsen manage as for MODERATE reaction – confirm that is obs for MODERATE are entered into EPR this generates MODERATE reaction pathway |  |  |
| 17.4 | The process for recording transfusion reactions must include manual, or electronic, entry of all required data sets, in accordance with BCSH guidelines  The system must support addition of further mandatory data sets if required by national guidelines | Confirmation of entry of observations into EPR  Note: acceptable for manual or electronic entry  Confirmation that additional observation date fields can be added if necessary |  |  |
| 17.5 | The system must include a process to apply blood component special requirements to the patient record, if this is recommended following investigation of the reaction (eg washed components, HLA matched components, use of anti-histamine or anti-pyretics prior to transfusion) | Confirmation that special requirements can be added to the patient record  Note: acceptable if this is a manual process following investigation of severe or moderate reaction |  |  |
| 17.6 | Any special requirements applied to the patient record following a transfusion reaction must appear every time a request for blood components/products is made | Confirmation that special requirement appears on patient record at every subsequent blood component/product order  Test for all special requirements:  HLA matched  Washed components  Anti-histamine cover for transfusion  Anti-pyretic cover for transfusion |  |  |
| 17.7 | The system must include instructions, and a link, to register the transfusion reaction on the Trust incident reporting system | Confirmation that EPR includes hyperlink to:  Transfusion Policy  Transfusion reaction flow chart  Confirmation that transfusion reaction episode is maintained in EPR patient history  Confirmation that full audit trail of actions taken are maintained on EPR patient record and are related to the transfusion reaction event |  |  |
|  |  |  |  |  |
| 18 | Administration module |  |  |  |
| 18.1 | The system must support safe administration of all blood components and products in accordance with BCSH, SHOT and any other national recommendations  This process must include confirmation and record of positive patient identification as part of the administration process, this may be a checklist format  Please detail how this is achieved | Confirmation that EPR supports safe administration process using the Electronic blood management Tx system  Confirmation that Electronic blood management Tx is accessible through the EPR BPAM module  Confirmation that administration of blood components/products cannot be completed with BPAM only tested with all blood component/product types:  Red cells  FFP  Cryo  Platelets  Octaplas  Albumin  IVIg  Anti-D  Anti-tetanus  Praxbind  PCC  Factor concentrates  Confirmation that Electronic blood management Tx is accessible on the EPR rover mobile devices  Confirmation that Electronic blood management Tx is accessible on EPR PC devices – for ITU only  Note: Electronic blood management Tx contains checklist and positive patient identification via ID band scanning |  |  |
| 18.2 | The system must include a full audit trail of the individual performing the pre-transfusion checks, including name, date/time of checks and verification that the checks have been performed | Confirmation that audit trail of administration activities is transferred from Electronic blood management to EPR:  Arrivals –  User identification (porter)  User identification (receiver)  Date/time of arrival  Component/product unique identification number  Component/product code  Begin transfusion:  User identification  Component/product unique identification number  Component/product code  Date/time of begin transfusion  Alerts generated by Electronic blood management :  Out of temperature storage excursion  Assigned to different patient  End transfusion:  User identification  Component/product unique identification number  Component/product code  Date/time of begin transfusion  Alerts generated by Electronic blood management :  Assigned to different patient |  |  |
| 18.3 | The pre-transfusion checklist must contain confirmation of the following (at a minimum):   * Verbal patient identification * Patient identification from the ID band * Pre-transfusion observations obtained and recorded * Correct giving set used * Blood group confirmed on the blood component and compatibility tag * Expiry date/time checked on component/product * Special requirements (link to any special requirements recorded on patient record, displayed for the user for confirmation with the component/product) | Note: this checklist is only required for contingency plan (when Electronic blood management down)  Confirmation that BPAM system contains checklist:   * Verbal patient identification * Patient identification from the ID band * Pre-transfusion observations obtained and recorded * Correct giving set used * Blood group confirmed on the blood component and compatibility tag * Expiry date/time checked on component/product * Special requirements (link to any special requirements recorded on patient record, displayed for the user for confirmation with the component/product)   Confirmation that BPAM mandates completion of the checklist by authorised user |  |  |
| 18.4 | The pre-transfusion check process must include confirmation that consent has been recorded, this must be electronically input from the request for component/product  If the transfusion is being given without consent (eg in emergency scenarios) there must be a fully auditable override process, including an alert and a process for recording consent post transfusion | Confirmation that BPAM checklist contains field for consent  This field should be automatically entered from information gained by medical staff during prescription process  In emergency consent override at administration:  Override has full audit trail – user, reason, date/time  Confirmation that EPR prompts user for transfusion consent at later date:  Consent field remains open – subsequent access to patient record prompts completion  Consent field can be closed on patient death |  |  |
| 18.5 | The administration process must contain a step for confirmation of right patient-right blood, this is a vital step for patient safety  This must include an electronic check of the patient details on the component/product compatibility label, the component/product and the patient ID band at the patient bedside  This process may be performed by the Electronic blood management system with the full details transmitted to the EPR via an interface  Please detail how this is achieved | Note – covered by Electronic blood management Tx  Required for contingency planning and validation covered by section 18.3 |  |  |
| 18.6 | The system must record how long the component/product has been out of the controlled storage area and advise the user on the time that the transfusion must be completed  The time to complete the transfusion must be user configurable and linked to specific components/products | Note: covered by Electronic blood management manager and Tx  Required for contingency planning:  Data field in BPAM for entering the time component/product removed from temperature controlled storage  EPR rules set for allowing no more than 30 minutes out of storage for blood components:  Red cells  FFP  Platelets  Cryo  EPR rules set for allowing no more than 72 hours out of storage for blood products:  Albumin  Anti-D  IVIg  Factor concentrates  Praxbind  PCC  Anti-tetanus |  |  |
| 18.7 | The system must recognise components/products that are labelled as “emergency” and are not allocated to a specific patient (eg red cells, FFP, Lyoplas, PCC)  When administration of an emergency component/product is started the user must be alerted that compatibility for the product has not been ascertained and that the clinician must take responsibility for the transfusion  Administration of emergency component/products must be performed using the same right-patient-right blood steps (18.2, 18.3 and 18.5)  Once administration of the emergency component/product has been commenced the system must link the patient identification with the unit identification and electronically transmit this information to the LIMS to provide full traceability of the component/product  The system must be configurable to include additional products as “emergency” as required by the organisation | Confirmation that EPR can receive information on emergency components/products from Electronic blood management Tx:  Red cells  FFP  PCC  Confirmation that EPR can link emergency transfusion event information from Electronic blood management Tx to patient record in EPR:  Component/product type  Unique component/product number  Component/product code  Date/time of begin transfusion  User completing begin transfusion  Date/time of end transfusion  User completing end transfusion  Confirmation that event is clearly identified in EPR as emergency event  Note: This is covered by Electronic blood management Tx  For contingency confirm that BPAM contains alert that the compatibility of the component has not been ascertained:  User must select YES to confirm they understand the risk associated with transfusion  Confirmation using BPAM contingency process  Confirmation that following emergency administration of red cells, FFP and/or PCC the patient information is transmitted to the LIMS  Note: this process may be performed directly by Electronic blood management Tx and LIMS  May only be required for contingency plan |  |  |
| 18.8 | The system must include a process for linking the pre-transfusion observations (eg temperature, blood pressure, pulse, respiratory rate), 15 minute observations and post-transfusion observations with an individual component transfusion  The system must include all observations according to the BCSH guidance, linked to specific requirements according to component/product type and be configurable to include additional observations as required | Confirmation that EPR links observation records with an individual transfusion episode  Confirmation that EPR mandates completion of all observation records  Confirmation that EPR alerts user to outstanding observation records  Confirmation that EPR generates reports on open transfusion observation records for monitoring and trend analysis |  |  |
| 18.9 | The pre-, 15 minute and post-transfusion observations must be subject to user configurable algorithms to identify potential transfusion reactions and alert the user  This process must link to the process for recording and investigating transfusion reactions | Confirmation that algorithms are functional and generate transfusion reaction process |  |  |
| 18.10 | The system must include a process for alerting users when observations are due or overdue  This process must be location/ward specific and only include transfusion occurring in the nominated area  Please detail how this is achieved | Confirmation that alerts of “open” transfusion observations are visible by ward staff on EPR dashboard  Confirmation that dashboard only displays alerts for that area |  |  |
| 18.11 | The system must include a process for advising the users on setting transfusion rate through a pump system | Confirmation that EPR information from LIMS includes the volume of the product/component  Confirmation that pump setting rate is generated in EPR based on volume and time stated for transfusion  Confirmation that transfusion time cannot be set >4 hours  Confirmation that volume cannot be set >300mls for blood components  Confirmation that volume cannot be set >500mls for blood products  EPR contains date field for nurse confirmation that pump has been set to correct rate  Confirmation that EPR retains all information relating to blood components/product volumes, transfusion times and calculated pump settings |  |  |
| 18.12 | The system must provide a process for alerting the user when a transfusion is overdue for completion | Confirmation that EPR dashboard includes alerts for transfusion overdue completion  Confirmation that visibility of alerts is confined to dashboard for relevant clinical area only |  |  |
| 18.13 | The system must be user configurable to fate the unit as “transfused” at begin transfusion or end transfusion  The fate of the unit must be electronically transmitted to the LIMS | Confirmation that EPR “fates” unit to patient at Electronic blood management begin transfusion  Confirmation that EPR “fates” unit at Electronic blood management end transfusion  Confirmation that fate is transmitted to LIMS (note: this may be performed via link from Electronic blood management to LIMS directly) |  |  |
| 18.14 | The system must include electronic fating of all blood components/products following administration where the Electronic blood management system, or equivalent, is used for administration. This must include the following details:   * Date/time of administration * Location of administration * Identification of individual administering the blood component/product * Product unique identification number * Product expiry date | Confirmation that EPR retains all following information:   * Date/time of administration * Location of administration * Identification of individual administering the blood component/product * Product unique identification number * Product expiry date |  |  |
| 18.15 | All information regarding administration of blood components/products as detailed in section 18 may be electronically transferred to the EPR from the Electronic blood management system or LIMS system via an interface | Note: acceptable if information is transmitted from LIMS to EPR if EPR cannot interface to Electronic blood management |  |  |
| 18.16 | The system must only allow access to authorised staff with in-date transfusion training and competency assessment  The system must include a warning mechanism to alert staff when transfusion training is near to the expiry date, please detail how this is achieved | Note: this function is controlled by Electronic blood management Tx  For contingency in Electronic blood management downtime it is accepted that EPR does not have the functionality to control authorised access to BPAM – ensure that this is covered in risk assessment and contingency plan |  |  |
| 18.17 | The blood component/product administration system must include a mechanism for alerting the user and the laboratory when there is a mis-match between the patient details on the ID band and those on the component/product | Note: this is covered by Electronic blood management Tx  For contingency in Electronic blood management downtime BPAM must alert user to mismatch:  Test using following scenarios:  Difference in surname  Difference in forename  Difference in Hospital number  Difference in NHS number  Difference in component/product unique number  Difference in component/product code  Confirm that BPAM does not require gender as part of patient identification |  |  |
| 18.18 | Warnings and alerts MUST include, but not be limited to the following:  a) Wrong pack for patient  b) Permitted time out of fridge limit exceeded (with override if applicable)  c) Unknown patient  d) Barcode misread  e) Expired unit | Note: controlled by Electronic blood management Tx  For contingency in Electronic blood management downtime confirm that EPR alerts user to:  Wrong pack for patient  b) Permitted time out of fridge limit exceeded (with override if applicable)  c) Unknown patient  d) Barcode misread  e) Expired unit |  |  |
| 18.19 | Warnings and alerts must be audible and visual to the user at the time of the alert and transmitted to the laboratory staff for review and resolution  Please detail how this is achieved. | Note: controlled by Electronic blood management Tx  For contingency in Electronic blood management downtime confirm that EPR alerts are visible and audible  Confirm that alerts are transmitted to laboratory staff |  |  |
| 18.20 | Contingency planning | Confirmation of contingency plan in place:  In the event of EPR planned/unplanned downtime:  Electronic blood management Tx used for administration – information is uploaded to EPR when system back up  In the event of Electronic blood management planned/unplanned downtime:  EPR BPAM system used for administration – two nurse double independent check mandated – ID band scanning mandated  Information is transmitted to LIMS  Confirmation that BPAM can only be unlocked by transfusion staff for this purpose  Confirmation that BPAM cannot be unlocked by any other member of staff |  |  |
|  |  |  |  |  |
| 19 | Cold Chain |  |  |  |
| 19.1 | The system must be capable of recording the date/time that the component/product was removed from a controlled storage area  This information may be electronically input from the Electronic blood management system/LIMS if not recorded directly by the EPR  Please detail how this is achieved | Note: controlled by Electronic blood management and LIMS  For contingency plan in Electronic blood management downtime confirm that BPAM can determine time out of controlled storage (as per 18.6) |  |  |
| 19.2 | The system must include a process for recording the arrival of a blood component/product into the clinical area, including the date/time, identification of the individual delivering the component/product and the individual receipting the component/product  This information may be electronically input from the Electronic blood management system/LIMS if not recorded directly by the EPR  Please detail how this is achieved | Note: controlled by Electronic blood management with interface to EPR  EPR contingency using BPAM – validated in section 18 |  |  |
| 19.3 | The system must include an alert at arrival and administration if the component/product has been out of controlled storage for an inappropriate time period  The allowable time period must be user configurable and specific for individual component/product types | Controlled by Electronic blood management  Contingency using BPAM validated in section 18 |  |  |
| 19.4 | The system must include a process for recording if a transfusion is commenced when a component/product has been out of controlled storage for longer than the specified time  The record must include the identification of the individual overriding the cold chain rule and the reason for override | Controlled by Electronic blood management  Contingency using BPAM confirmed that BPAM allows transfusion with override  Confirmation that override includes – user, reason (free text), date/time  Confirmation the EPR generates reports for cold chain excursions for monitoring and trend analysis |  |  |
| 19.5 | All alerts must be presented to the user and sent to the laboratory system for resolution | Confirmation that all the above alerts are visible to the user  Confirmation that alert reports can be generated in EPR |  |  |
|  |  |  |  |  |
| 20 | Installation & Operation Qualification |  |  |  |
| 20.1 | The supplier must provide a detailed implementation and installation project plan with timescales. | For information only |  |  |
| 20.2 | The supplier must perform the installation and operational qualification validation steps for the system | Confirm that these have been received and signed as approved by transfusion manager/quality manager |  |  |
| 20.3 | The supplier must support the laboratory performance qualification/verification as defined by the laboratory, including all costs, to meet the standards required by ISO 15189 and BSQR. | Covered by EPR contract  Standards for ISO15289 and BSQR validated by the plan |  |  |
| 20.4 | The system mustoperate for its lifetime in accordance with ISO 15189 and BSQR standards | For information only – system subjected to regular re-validation after software upgrades  Confirmation that transfusion manager/quality manager will be made aware of planned upgrades |  |  |
| 20.5 | The supplier must provide an installation and an operational risk assessment for the use of their system. | For information only |  |  |
| 20.6 | The supplier must ensure full service provision is maintained during implementation/works.  Details of how this will be achieved must be specified | For information only |  |  |
| 20.7 | A fully competent company representative **MUST** be available on site until the installation is complete and units are functioning satisfactorily. | For information only |  |  |
| 20.8 | All software upgrades and their subsequent validation/verification to meet ISO 15189 and BSQR **MUST** be fully supported by the supplier and be free of charge | For information only  Confirm that transfusion manager/quality manger will be sent release notes for software upgrades in reasonable time frame to allow validation  Confirm that EPR has a test site that can be linked to test Electronic blood management and test LIMS for re-validation |  |  |
|  |  |  |  |  |
| 21 | Operation and Maintenance |  |  |  |
| 21.1 | Supplier must guarantee a maximum response time by an engineer/ application specialist of 30 minutes from reporting a fault during 9 to 5.30 (core hours). | For information only – covered by My Care contract team |  |  |
| 21.2 | Supplier must guarantee a maximum response time from fault reporting to engineer visit/escalation of 8 working hours | For information only – covered by My Care contract team |  |  |
| 21.3 | Supplier must provide 24/7 support for breakdowns. | For information only – covered by My Care contract team |  |  |
| 21.4 | All software upgrades during the length of the contract must be included and installed in a timely manner as soon as available. | For information only – covered by My Care contract team |  |  |
| 21.5 | The supplier must provide release notes prior to all software upgrades in a time that allows validation preparation | For information only – covered by My Care contract team |  |  |
| 21.6 | Should the laboratory change its LIMS/Blood Tracking system, interfacing replacement must be provided for by the supplier at no additional cost | For information only – covered by My Care contract team |  |  |
| 21.7 | Supplier must state how archiving of data is achieved | Confirmation of data archiving process – information from IMT |  |  |
|  |  |  |  |  |
| 22 | Training |  |  |
| 22.1 | The supplier must detail the training requirements for the system including duration of any training courses normally included in the supply of the analyser. | My Care process commenced February 2019 – ongoing meetings with MY Care tam to ensure build on target |  |
| 22.2 | The supplier must provide advanced training for at least two members of staff for the solution | Who are the transfusion team with advanced training ???? |  |
| 22.3 | The supplier must provide on-site training for all system operators | Training supported by Kate Rose |  |
| 22.4 | The supplier must give details of any user groups.  If a cost is attached to attendance of these meetings it should be shown here. | For information only – covered by My Care contract team |  |
| 22.5 | On-going training mustbeprovided as required following significant changes to software or hardware or laboratory staff. | For information only – covered by My Care contract team |  |

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| **Clinical data sets for transfusion – to be configured in the LIMS and EPR system** |  |  |  |
| Gastrointestinal  GI-Oesophageal  GI-Gastric  GI-Pancreatic  GI-Liver surgery  GI-Colorectal  GI-Other surgery  GI-Upper GI bleed (non-variceal)  GI-Upper GI bleed (variceal)  GI-Lower GI bleed  GI-Liver failure  GI-Pancreatitis | Note: information relating to reason for transfusion will be extracted from EPR admission information  Confirm that this information is translated into national indication codes  Confirm that EPR generates reports based on:  Indication codes  Single unit transfusions  Pre and post-Hb levels  Overrides  Appropriate transfusions  Inappropriate transfusions |  |  |
| Genitourinary  GU-Cystectomy  GU-Nephrectomy  GU-Prostatectomy  GU-Other surgery |  |  |  |
| Gynaecology  Gyn-Surgical malignancy  Gyn-Surgical non-malignant  Gyn-Non surgical |  |  |  |
| Maxillo-facial Surgery  Plastic Surgery |  |  |  |
| Neurosurgery  Neuro-Intracranial bleeding  Neuro -Malignancy  Neuro -Spinal  Neuro -Other surgery |  |  |  |
| Obstetrics  Obs-APH  Obs-PPH  Obs-Placenta praevia  Obs-DIC  Obs-Caesarean section  Obs-Other surgery |  |  |  |
| Orthopaedics  Ortho-Primary Hip  Ortho-Redo Hip  Ortho-Primary Knee  Ortho- redo Knee  Ortho-Spinal  Ortho-Other surgery  Ortho-RTA  Ortho-# femur  Trauma-  Burns |  |  |  |
| Transplant  Trans-Heart  Trans-renal  Trans-renal/pancreas  Trans-Liver  Trans-Lung  Trans-Pancreas  Trans-Small Bowel |  |  |  |
| Renal  Renal-CRF  Renal-ARF |  |  |  |
| Vascular  Vasc-Elective AAA  Vasc-Emergency AAA  Vasc-Leg artery grafts |  |  |  |
| Haematology  Haem-Aplastic anaemia  Haem-AML  Haem-ALL  Haem-MDS  Haem-MPD  Haem-Chronic leukaemia  Haem-Lymphoma  Haem-Myeloma  Haem-Iron deficiency  Haem-B12/folate deficiency  Haem-Anaemia of chronic disorders  Haem-Haemolysis acquired  Haem-Haemolysis congenital  Haem-Sickle cell disease  Haem-Thalassaemia  Haem-ITP  Haem-Congenital platelet disorder  Haem-DIC  Haem-TTP  Haem-Reversal of warfarin  Haem- single factor deficiency  Infection-Malaria |  |  |  |
| Oncology  Onc-Chemo  Onco-Anaemia of malignancy  Onco-Radiotherapy |  |  |  |
| Paediatics  Paed- exchange transfusion  Paed- top up transfusion  Paed-Neonatal alloimmune thrombocytopenia  Paed-Sepsis |  |  |  |
| Procedure  Pro-Ascitic tap  Pro-Chest drain  Pro-Endoscopy  Pro-ERCP  Pro-Laparoscopy  Pro-Line Insertion  Pro-Liver biopsy  Pro-Lumbar puncture  **Clinical Transfusion Dataset**  **Data item Source of data Mandatory (M) or desirable (D)?** |  |  |  |
| **Group and screen** |  |  |  |
| Patient identifier  Transfusion request into LIMS  M |  |  |  |
| Consultant responsible for care  Transfusion request into LIMS  D |  |  |  |
| Clinical Specialty  Transfusion request into LIMS  M |  |  |  |
| Year of birth  Transfusion request into LIMS  M |  |  |  |
| Gender  Transfusion request into LIMS  M |  |  |  |
| Previous transfusion history  Transfusion request into LIMS  D |  |  |  |
| Previous obstetric history  Transfusion request into LIMS  D |  |  |  |
| **Blood component order** |  |  |  |
| Patient identifier  Transfusion request into LIMS  M |  |  |  |
| Consultant responsible for care  Transfusion request into LIMS  D |  |  |  |
| Clinical Speciality  Transfusion request into LIMS  M |  |  |  |
| Year of birth  Transfusion request into LIMS  M |  |  |  |
| Gender  Transfusion request into LIMS  M |  |  |  |
| Previous transfusion history  Transfusion request into LIMS  D |  |  |  |
| Previous obstetric history  Transfusion request into LIMS  D |  |  |  |
| Number of units (mL) required  Transfusion request into LIMS  M |  |  |  |
| Coded clinical reason for use  Transfusion request (selected by the requester)  M |  |  |  |
| Truncated National Indication Code  Transfusion request (selected by the requester)  M |  |  |  |
| Has consent been documented?  Transfusion request into LIMS  M |  |  |  |
| Was the patient transfused? Yes / No  LIMS  M |  |  |  |
| Date of transfusion  LIMS  M |  |  |  |
| Time of transfusion  LIMS  M |  |  |  |
| **Transfused component (ISBT)**  **LIMS**  **M** |  |  |  |
| Blood group of transfused component  LIMS  M |  |  |  |
| Blood group of patient  LIMS  M |  |  |  |
| Expiry date of component  LIMS  M |  |  |  |
| Pre transfusion lab test result (coag, Hb, plts)  LIMS - Haematology  M |  |  |  |
| Post transfusion lab test result (coag,Hb, Plts)  LIMS - Haematology  M |  |  |  |
| Hb 14-42 days pre op (if date of procedure known) |  |  |  |
| **LIMS - Haematology**  M |  |  |  |
| Immediate Pre op Hb (if date / time of procedure known)  LIMS - Haematology  M |  |  |  |
| Discharge Hb (if date of discharge known)  LIMS - Haematology  M |  |  |  |
| Date of admission  PAS  M |  |  |  |
| Date of discharge / death  PAS  M |  |  |  |
| Did patient die in this admission?  PAS  M |  |  |  |
| ICD10 code (diagnostic code code)  PAS  M |  |  |  |
| OPCS4 code (procedure code)  PAS  M |  |  |  |
| HRG code  PAS  M |  |  |  |
| Date and time of procedure  PAS  M |  |  |  |
| Adverse event?  Not currently collected  D |  |  |  |
| Near patient test result: Hb, coag, TEG/ROTEM, plt function test  LIMS - Haematology  D |  |  |  |
| Was cell salvage used?  Theatre record  D |  |  |  |
| Volume of salvaged red cells returned  Theatre record  D |  |  |  |
| Was tranexamic acid prescribed?  Paper prescription / electronic prescription  D |  |  |  |
| Was the prescriber trained in blood ordering?  Collected as part of transfusion request  D |  |  |  |
| **Categories of Justification for Transfusion to Support Appropriate Use**  **Red cell concentrates** |  |  |  |
| R 1  Acute bleeding with BP instability |  |  |  |
| R 2  Hb ≤ 70 g/L in stable ICU patient |  |  |  |
| R 3  Hb ≤ 80 g/L non-ICU patient with signs/symptoms of anaemia |  |  |  |
| R 4  Hb ≤ 100 g/L with acute cardiac ischaemia |  |  |  |
| R 5  Surgical blood loss anticipated |  |  |  |
| R 6  Other (free text) |  |  |  |
| **Fresh frozen plasma** |  |  |  |
| F 1  Massive bleeding |  |  |  |
| F 2  INR ≥ 1.6 with bleeding |  |  |  |
| F 3  INR ≥ 1.6 and pre-procedure |  |  |  |
| F 4  Therapeutic exchange |  |  |  |
| F 5  Other (free text) |  |  |  |
| **Cryoprecipitate** |  |  |  |
| C 1  Active bleeding |  |  |  |
| C 2  Fibrinogen ≤ 1.0g/l & pre-procedure |  |  |  |
| C 3  Other (free text) |  |  |  |
| **Platelets** |  |  |  |
| P 1  PLT count ≤ 10 x 109/l stable patient |  |  |  |
| P 2  PLT count ≤ 20 x 109/l with platelet consumption |  |  |  |
| P 3  PLT count ≤ 50 x 109/l pre-procedure |  |  |  |
| P 4`  Bleeding on anti-PLT medication |  |  |  |
| P 5  Massive bleeding |  |  |  |
| P 6  Other (free text) |  |  |  |

**Transfusion order comms and EPR – Evaluation Criteria**

**PASS/FAIL** – A fail on any of these questions will result in your company not being taken any further in the procurement process.

**YES / NO** - This will determine whether you meet the standard or not and will attract a score of either 0 for a NO and 5 for a YES.