# IV with solid fillINVITATION TO SUPPLY A TRANSFUSION ORDER COMMS/EPR SOLUTION EPR

**TRANSFUSION SERVICES**

**INTRODUCTION**

**INSTRUCTIONS FOR BIDDERS**

* The enclosed specification represents the technical requirements that the chosen information management system has to meet. Prospective suppliers, who are or will be unable to meet these, will not be considered further. If there are any areas of the specification that are under development, these **MUST** be clearly indicated with a statement regarding availability.
* Please respond to the technical specification by the stated deadline.
* Throughout this document the use of the word ‘system’ may be taken by the supplier to mean all equipment proposed as part of the package.
* The solution proposed may contain specific information technology from more than one supplier but **MUST** be presented as a single solution.
* The supplier must be able to conform to the specification or give a reasonable alternative. If unable to conform, please state the reason.
* It is a requirement that the current laboratory output must be maintained during installation and acceptance testing of the offered system.
* The supplier will be expected to give detailed guarantees that they can meet all standards of ISO15189 concerning information management systems. This must include written detail of how they will meet the verification and validation criteria.
* For scored questions, where there is an opportunity for a highest score; all other scores will be relative to how far away they are from their highest scoring answer
* Please complete the accompanying pricing spreadsheets

* The successful contractor will be required to meet and maintain the standards set out in the Specification and related key performance Indicators (outlined in the document ’KPIs’) throughout the term of the contract. A copy of the KPI’s are provided by Roche for you to review consider and comment on as part of this process. Failure to consistently meet these obligations may lead to early termination of the contract at the contractor’s expense

* A copy of the Sub Contract has also been provided for your information
* Appendices will be accepted please label using the question number it is associated with and the name of the attachment e.g. 1.1 Example of Reference sites UK. While there are no word count limits, responses should be clear, concise and relevant to the specific requirement. Should bidders have any questions relating to the tender these can be asked through the designated contact with the designated clarification window.

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| **Question**  **Number** | **Question** | **How to Score** |
| **1** | Essential System Requirements |  |
| 1.1 | There must be bidirectional interfaces between the EPR, the LIMS and Electronic blood management system systems. | Pass/Fail |
| 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 | Pass/Fail |
| 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. | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 1.7 | All upgrades to the system must be supplied free of charge | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 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) | Pass/Fail |
| 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 |  |
| 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) |  |
| 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 |  |
| 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 |  |
| 1.15 | When a request is generated for red cells for confirmed transfusion the system must be capable of generating the prescription |  |
| 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 |  |
| 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) |  |
| 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 |  |
| 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 |  |
| 1.20 | The system must interface to the LIMS to transfer the request to the LIMS system for laboratory action |  |
| 1.21 | The system must operate in accordance with all national recommendations for blood transfusion, including, but not limited to BSH, BSQR, ISO15189, Department of Health |  |
| 1.22 | The system must be capable of receiving information from the LIMS/Electronic blood management system 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 |  |
| 1.23 | **Pick up slip requirement, must be compatible with Electronic blood management system**  Must have legible print  Must have a functional barcode that can be read by the EBMS 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 |  |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 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 system or the LIMS, please state how this is achieved | Pass/Fail |
| 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 | Pass/fail |
| 2.5 | The reports generated must be available in multiple formats including bar charts, line graphs, crosstabs | Pass/fail |
| 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 | Yes/No  Weighting:  Most comprehensive system scores highest |
| 2.7 | The system must support a formal pre-transfusion risk assessment for transfusion-associated circulatory overload (TACO), in accordance with SHOT recommendations | Pass/fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/fail |
| 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 | Pass/fail |
| 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 | Pass/Fail |
| 2.14 | All patient test results supporting the clinical advisory service must be electronically transferred from the haematology/chemistry LIMS where relevant. | Pass/Fail |
| 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) | Pass/Fail |
| 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 | Pass/Fail |
| 2.17 | The system must include appropriate rules to determine whether a blood sample is required based on information supplied from the LIMS |  |
| 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) | Pass/Fail |
| 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 |  |
| 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 |  |
| 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 |  |
| 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. |  |
| 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 |  |
| 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 |  |
| 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 |  |
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| 3 | Sample Collection (Order Comms) |  |
| 3.1 | The sample collection process must conform with the Guideline for the  Administration of Blood Components (BSH 2017)  Please specify details on how assurance that the sample is labelled at the patient side is achieved | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 3.4 | The system must include a clear warning of the dangers associated with wrong blood in tube events | Pass/Fail |
| 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) | Pass/Fail |
| 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 | Pass/Fail |
| 3.7 | The system must support a process for communication to the requestor of samples that have been rejected, including the reason for rejection | Pass/Fail |
| 3.8 | The system must include advice on the sample type required, based on the test requested and including:   * Volume * Anticoagulant, if required |  |
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| 4 | Requesting red cells |  |
| 4.1 | The system must support appropriate requesting of red cells in accordance with current BSH guidelines  The system must be user configurable to enable support of any changes to appropriate use of red cells, or local adaptations | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 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 |  |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 4.7 | The system must only accept FBC parameter triggers (Hb, MCH) from an FBC sample taken in the previous 24 hours |  |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 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 system to provide this capability  Please detail how this is achieved | Pass/Fail |
| 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) | Pass/Fail |
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| 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 | Pass/Fail |
| 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 |  |
| 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 | Score (Most straight-forward scores highest)  Weighting: 3 |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 5.6 | The system must only accept coagulation parameter triggers (PT, APTT, fibrinogen) from a coagulation sample taken in the previous 6 hours | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 5.9 | The system must support weight-adjusted FFP/Cryoprecipitate dosing to guide the appropriate volume (mls) required for all paediatric and neonatal patients | Pass/Fail |
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| 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 | Pass/Fail  Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 6.5 | The system must only accept platelet count triggers from an FBC sample taken in the previous 24 hours | Pass/Fail |
| 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 |  |
| 6.7 | The system must support weight-adjusted platelet concentrate dosing to guide the appropriate volume (mls) required for all paediatric and neonatal patients | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
|  |  | Pass/Fail |
| 7 | Requesting anti-D |  |
| 7.1 | The system must support appropriate requests for anti-D for potentially sensitising events and for routine antenatal anti-D prophylaxis (RAADP) based on patient D-type, presence of immune anti-D, cffDNA screening result for current pregnancy | Pass/Fail |
| 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 | Pass/Fail |
| 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 |  |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 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 |  |
| 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 |  |
| 7.9 | The system must support a process for recording when a patient has declined anti-D, including the reason for refusal |  |
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| 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” | Pass/Fail |
| 8.2 | The system must link to external systems, if required, for NHS England high cost drug ordering (eg BlueTeq) | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 8.6 | The system must automatically assign a dosing regimen depending on the indication for the request (eg 1g/kg for ITP) | Pass/Fail |
| 8.7 | The system must include a process for approval of the request from a designated IVIg panel member | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
|  |  | Pass/fail |
| 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 | Pass/Fail |
| 9.2 | The system must support requests for all available concentrations of HAS (20%, 4.5% and 5%) | Pass/Fail |
| 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 | Pass/Fail |
| 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 |  |
|  |  | Pass/Fail |
| 10 | Requesting factor concentrates | Pass/Fail |
| 10.1 | The system must support requests for factor concentrates in accordance with user definable criteria | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 10.4 | The system must provide a link to information regarding the reconstitution and safe administration of the product | Pass/Fail |
|  | 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 |  |
|  |  |  |
| 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) | Pass/Fail |
| 11.2 | The system must support requests for all available concentrations of PCC (1000iu and 500iu) | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 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) | Pass/Fail |
| 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 | Pass/Fail |
| 11.8 | The system must provide a link to information regarding the reconstitution and safe administration of the product | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
|  |  |  |
| 12 | Requesting anti-tetanus |  |
| 12.1 | The system must support request for anti-tetanus | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
| 13 | The system must provide a link to information regarding the safe administration of the product |  |
| 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 | Pass/Fail |
|  |  | Pass/Fail |
| 14 | Requesting C1 esterase inhibitor concentrate |  |
| 14.1 | The system must support request for C1 EIC | Pass/Fail |
| 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 | Pass/Fail |
| 14.3 | The system must provide a link to information regarding the reconstitution and safe administration of the product | Pass/Fail |
| 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 | Pass/Fail |
| 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 | Pass/Fail |
|  |  | Pass/Fail |
| 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 | Pass/Fail |
| 15.2 | The system must support entry of the reason for request, including set user definable criteria and free text entry | Pass/Fail |
| 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 |  |
| 15.4 | The system must provide a link to information regarding the reconstitution and safe administration of the product |  |
| 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) |  |
| 15.6 | The system must provide advice for reversal of DOAC where there is a specific agent available |  |
| 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 |  |
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| 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 |  |
| 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 |  |
| 16.3 | The system must provide a dose calculation process based on patient weight and reason for request |  |
| 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 |  |
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| 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 |  |
| 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) |  |
| 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 |  |
| 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 |  |
| 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) |  |
| 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 |  |
| 17.7 | The system must include instructions, and a link, to register the transfusion reaction on the Trust incident reporting system |  |
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| 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 |  |
| 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 |  |
| 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) |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 18.11 | The system must include a process for advising the users on setting transfusion rate through a pump system |  |
| 18.12 | The system must provide a process for alerting the user when a transfusion is overdue for completion |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 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. |  |
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| 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 |  |
| 19.2 | The system mist 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 |  |
| 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 |  |
| 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 |  |
| 19.5 | All alerts must be presented to the user and sent to the laboratory system for resolution |  |
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| 20 | Installation & Operation Qualification |  |
| 20.1 | The supplier must provide a detailed implementation and installation project plan with timescales. |  |
| 20.2 | The supplier must perform the installation and operational qualification validation steps for the system |  |
| 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. |  |
| 20.4 | The system mustoperate for its lifetime in accordance with ISO 15189 and BSQR standards |  |
| 20.5 | The supplier must provide an installation and an operational risk assessment for the use of their system. |  |
| 20.6 | The supplier must ensure full service provision is maintained during implementation/works.  Details of how this will be achieved must be specified |  |
| 20.7 | A fully competent company representative **MUST** be available on site until the installation is complete and units are functioning satisfactorily. |  |
| 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 |  |
|  |  |  |
| 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). |  |
| 21.2 | Supplier must guarantee a maximum response time from fault reporting to engineer visit/escalation of 8 working hours |  |
| 21.3 | Supplier must provide 24/7 support for breakdowns. |  |
| 21.4 | All software upgrades during the length of the contract must be included and installed in a timely manner as soon as available. |  |
| 21.5 | The supplier must provide release notes prior to all software upgrades in a time that allows validation preparation |  |
| 21.6 | Should the laboratory change its LIMS/Blood Tracking system, interfacing replacement must be provided for by the supplier at no additional cost |  |
| 21.7 | Supplier must state how archiving of data is achieved |  |
|  |  |  |
| 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. |
| 22.2 | The supplier must provide advanced training for at least two members of staff for the solution |
| 22.3 | The supplier must provide on-site training for all system operators |
| 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. |
| 22.5 | On-going training mustbeprovided as required following significant changes to software or hardware or laboratory staff. |

**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.