

NHS Forth Valley

Local Report ~ May 2008

Blood Transfusion

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Blood Transfusion

NHS Quality Improvement Scotland (NHS QIS) is committed to equality and diversity. We have assessed the performance assessment function for likely impact on the six equality groups defined by age, disability, gender, race, religion/belief and sexual orientation. For this equality and diversity impact assessment, please see our website (www.nhshealthquality.org). The full report in electronic or paper form is available on request from the NHS QIS Equality and Diversity Officer.

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1 Setting the scene

NHS Quality Improvement Scotland (NHS QIS) was set up by the Scottish Parliament in 2003 to take the lead in improving the quality of care and treatment delivered by NHSScotland. NHS QIS does this by setting standards and monitoring performance, and by providing NHSScotland with advice, guidance and support on effective clinical practice and service improvements.

The Scottish National Blood Transfusion Service (SNBTS) is responsible for collecting, processing, storing and supplying all blood and blood components in Scotland and NHS boards are responsible for ordering and managing their supplies in a safe and effective manner. The Scottish Executive introduced a programme of work to improve and support transfusion practice in Scotland and, as a consequence, NHS QIS appointed a project group to develop clinical standards for blood transfusion practices. The project group developed four standards, covering: core principles; clinical management – pre-transfusion; clinical management – hospital transfusion laboratory; and clinical management – blood and blood component collection, administration and monitoring. The Clinical Standards for Blood Transfusion were published in September 2006. These include details of the project group which set the standards and are available on request from NHS QIS or can be downloaded from the website (www.nhshealthquality.org).

About this report

This report presents the findings from the peer review of **NHS Forth Valley's** performance against the blood transfusion standards.

The review process has three key phases: preparation prior to the visit; the visit; and the report production and publication following the visit. (See flow chart in Appendix 2 for further detail.) During the visit, each multidisciplinary review team assesses performance using the categories 'met', 'not met' and 'not met (insufficient evidence)', as detailed below.

- **'Met'** applies where the evidence demonstrates the standard and/or criterion is being attained.
- **'Not met'** applies where the evidence demonstrates the standard and/or criterion is not being attained.
- **'Not met (insufficient evidence)'** applies where no evidence is available for the review team, or where the evidence available is insufficient to allow an assessment to be made.

A final category **'not applicable'** is used where a standard and/or criterion does not apply to the NHS board under review.

Each review team is led by an experienced reviewer, who is responsible for guiding the team in their work and ensuring that team members are in agreement about the assessment reached. Membership of the review team visiting **NHS Forth Valley** on **6 February 2008** can be found in Appendix 3.

2 Summary of findings

2.1 Overview of local service provision

Forth Valley is situated in central Scotland and has a population of around 286,053¹. While Forth Valley comprises both urban and rural areas, the majority of the population live in urban areas, of which Falkirk and Stirling are the largest.

Local NHS system and services

Forth Valley NHS Board is responsible for improving the health of the local population and for the delivery of the healthcare required. It provides strategic leadership and has responsibility for the efficient, effective and accountable performance of the NHS in Forth Valley.

At the time of the review visit, NHS Forth Valley was a single integrated system comprising acute hospital services, and community based services which are delivered through three community health partnerships in Clackmannanshire, Falkirk and Stirling.

Further information about the local NHS system can be accessed via the website of NHS Forth Valley (www.show.scot.nhs.uk/nhsfv/index.html).

The NHS Forth Valley's hospital blood bank is in the laboratory department of Stirling Royal Infirmary (SRI) and provides serology and blood issue for all areas of NHS Forth Valley. The blood bank receives blood and blood components from the West of Scotland SNBTS (Clinical Directorate) hospital transfusion laboratory (WOSBTS) based at Gartnavel Hospital, Glasgow.

SRI supplies Falkirk & District Royal Infirmary (FDRI) haematology laboratory and Strathcarron Hospice, Denny, with blood and blood components, as required. The WOSBTS also supplies blood and blood components to Abbey King's Park Hospital, Stirling.

In the 12 months prior to the review visit, approximately 9,300 red cell units were transfused.

The NHSScotland Better Blood Transfusion Programme (BBTP) is supported by a transfusion practitioner who works across all NHS Forth Valley hospital sites. The transfusion practitioner is assisted by five other BBTP trainers.

¹ General Register Office for Scotland. Mid-2006 Population Estimates Scotland: Population Estimates by Age and Sex and Administrative Area. First published on 26 April 2007. Revised 27 July 2007. Available from: <http://www.gro-scotland.gov.uk/files>

2.2 Summary of findings against the standards

A summary of the findings from the review is presented in this section. A detailed description of performance against the standards/criteria is included in Section 3.

Core principles

NHS Forth Valley has an established multidisciplinary hospital transfusion committee (HTC) which meets quarterly and reports to the acute services clinical governance working group. This working group is chaired by NHS Forth Valley's chief operating officer. The HTC remit includes promotion of best practice through local blood transfusion protocols which are based on national guidelines. Whilst audit activity related to the blood transfusion standards has been taking place, this has not been multidisciplinary and there has been limited resource for the HTC to act on the audit findings.

There is a highly committed operational transfusion team which promotes the targets of the NHSScotland BBTP. The team is led by the BBTP clinical lead who also sits on the HTC. The transfusion practitioner is an active member of the transfusion team and also sits on the HTC.

Any laboratory-related blood transfusion incidents are investigated by the laboratory quality manager. The transfusion practitioner investigates all such clinical-related incidents and follows up with relevant staff, providing retraining as necessary. The review team encouraged the board to ensure that the HTC was more actively involved in implementing corrective and preventative change to protocols following the transfusion practitioner's investigations.

NHS Forth Valley uses a 'bag and tag' system to ensure that every unit of blood component received into the SRI laboratory can be unmistakably traced to its recipient, or to its final fate if not transfused. There is a dedicated medical laboratory assistant with responsibility for the traceability of all units.

The minimum identification data set specified to be used at every stage of the blood transfusion process in NHS Forth Valley includes full name, gender, date of birth and a unique identifier. Audit findings, however, showed that not all patients were wearing wristbands, and that not all wristbands bore the unique identifier. For patients whose identity cannot be confirmed, a minimum of gender and a unique identifier would be included on their wristband. Phlebotomists confirmed that they would not take a blood sample without the patient wearing a wristband. A risk assessed alternative to a wristband had not been agreed. This will be addressed when the NHS Forth Valley identification policy is implemented. Staff are aware that patients have an option to refuse blood transfusion and there is a system in place to alert qualified practitioners to the existence of an advance directive or special requirements. The board has a strategy for management of blood shortages.

Clinical management – pre-transfusion

An audit of transfusion documentation has identified that the reasons for transfusion are being discussed with the patient, however, there was no evidence in the patient notes of the discussion of alternatives to transfusion or the option to refuse. A comprehensive transfusion care pathway form has been developed which includes prompts about the discussions and blood transfusion explanatory leaflets. The pathway has been piloted in FDRI and staff reported that this had significantly improved compliance with the blood transfusion standards.

Where pre-transfusion discussion is not possible, for example in accident and emergency if the patient is unconscious, action would be taken to establish if the patient had an advance decision document including a search on NHSScotland's Emergency Care Summary utility if partial identity could be established. Information leaflets, explaining the risks and benefits of transfusion would be offered to such patients on their discharge.

Positive patient identification at the time of blood sampling is included in all BBTP training, however, audit had identified that wristbands were not always in place and that the unique identifier was not always present on the wristbands. Prescriptions for blood units are signed by a qualified practitioner and are adequately detailed.

Clinical management – hospital transfusion laboratory

The transfusion laboratories at FDRI and SRI are accredited by Clinical Pathology Accreditation (UK) Ltd (CPA). The SRI blood bank is preparing for an inspection by the Medicines and Healthcare products Regulatory Agency (MHRA) and has a challenging action plan in place. Competency-based training and assessment systems have been implemented and training records are maintained.

NHS Forth Valley commissions services for NHS patients from Abbey King's Park Hospital and has suitable arrangements in place to ensure that the provider complies with current regulatory requirements.

There are protocols in place to optimise blood use and minimise wastage although, at the time of the review visit, the laboratory was using a paper-based stock management system and could not contribute to the national transfusion epidemiology database. The review team noted that the implementation of the recently purchased Blood Track® system would be a challenge for the board, but it would be a more robust system and would provide for more efficient stock management. The review team encouraged laboratory staff to participate in multidisciplinary audit.

Clinical management – blood and blood component collection, administration and monitoring

The BBTP training programme, delivered by the transfusion practitioner and five other trainers, emphasises that only staff who have undertaken BBTP training appropriate to their role participate in the blood transfusion process. Positive patient identification is highlighted in the BBTP training, although audit had identified that

not all patients were found to be wearing a wristband and not all wristbands included the unique identifier.

Protocols are in place for the monitoring of patients immediately before and during blood transfusion and any untoward events (including suspected adverse reactions) are immediately clinically managed and reported promptly to the hospital transfusion laboratory. Observational audit of transfusion episodes indicated that the protocol was not always being followed, although the new transfusion pathway form assists with this. Serious adverse events or reactions and near miss incidents are submitted to the relevant regulatory and reporting bodies.

3 Detailed findings against the standards

Standard 1a: Core Principles

Standard Statement

There are systems in place supporting clinical governance to ensure safe, effective and appropriate blood transfusion.

NHS Forth Valley

Essential Criteria

1a.1: There is an established, active, multidisciplinary hospital transfusion committee (HTC) that has defined responsibilities and accountability to the chief executive/NHS board via the clinical governance structure.

STATUS: Met

There is an established, multidisciplinary NHS Forth Valley hospital transfusion committee (HTC), with a ratified constitution and remit, which meets quarterly and follows a standing agenda. A consultant anaesthetist has been recently appointed as the committee chair, and staff reported that expanded representation from further blood user groups such as surgery and primary care, was being actively followed up. The review team noted the significant improvement in user representation on the HTC in the last year and acknowledged the challenge for the board to further broaden its membership.

The head of clinical governance sits on the HTC and on the acute services clinical governance working group to which the HTC reports. This working group is chaired by NHS Forth Valley's chief operating officer and reports up to the NHS Forth Valley clinical governance committee (CGC) with which it shares membership.

1a.2: The HTC has roles and responsibilities as outlined in MEL(1999)9 and HDL(2003)19. These include involvement in multi-professional audit, education and training, development and modification of guidelines and protocols, and involvement of stakeholders.

STATUS: Not met

NHS Forth Valley's HTC has a documented constitution and remit which includes promotion of best practice through local protocols based on national guidelines; commissioning of blood transfusion related audits; promotion of education and training and incident monitoring.

The review team noted that several useful audits had been conducted, although these had been instigated by the clinical lead for blood transfusion and the transfusion practitioner. There had not been multi-professional HTC involvement in these audits and the topics had not, at the time of the review visit, been re-audited in order to

demonstrate improvements following retraining. With the appointment of a consultant anaesthetist, as chair of the HTC, the board anticipated more involvement of all blood user groups in audit.

The transfusion practitioner provides an update on NHSScotland's Better Blood Transfusion Programme (BBTP) training at each HTC meeting, and is working towards the production of local unit BBTP training plans. The review team acknowledged the level of BBTP trained staff, in all groups, as an achievement.

There was limited evidence of protocols having been changed by the HTC, as a result of audit findings, or the committee's review of incidents. Staff reported that although the HTC had no resource to prepare an action plan to address all audit findings, the clinical governance working group would support the progress of such plans. It was also reported that mechanisms were in place to cascade out changes in practice through the safe and effective care committee feeding back to general managers, service managers and individual unit clinical governance groups. The review team encouraged the board to clarify and document the remit of the HTC to ensure that the HTC could promote improvement in practice, through review and initiation of modification of local protocols in line with national guidelines.

The transfusion practitioner maintains a register of all blood transfusion-related protocols and their distribution to all relevant units. The transfusion practitioner personally distributes revised protocols, and retrieves and destroys the previous version. The hospital transfusion team plan to integrate this register into an electronic quality management system (iPassport™) which is already in use in the laboratories. This system will then automatically email the clinical lead for transfusion and the transfusion practitioner with prompts to review protocols at the relevant times.

1a.3: The HTC, in collaboration with the clinical governance committee, implements the NHSScotland Better Blood Transfusion Programme (BBTP).

STATUS: Met

The review team noted that there was a highly committed operational transfusion team in place to fulfil the objectives and aims of the HTC. This team meets every 4-6 weeks and is chaired by the BBTP clinical lead who also sits on the HTC. The transfusion practitioner is an active member of this team, as well as the HTC, NHS Forth Valley acute services safe and effective care committee, and NHS Forth Valley acute services patient safety group. This provides opportunities for the transfusion practitioner to engage with all clinical units and promote the targets of the BBTP throughout NHS Forth Valley.

At the time of the review visit, the laboratory was not able to participate in the BBTP Scottish Transfusion Epidemiology Database that would inform users and providers

about the extent and the outcome of the use of blood. Staff reported that this is being addressed by the board.

1a.4: The HTC reviews all reports of adverse events and near miss incidents relating to blood transfusion and, in response, implements changes in practice where necessary.

STATUS: Not met

Blood transfusion-related incidents occurring at any blood transfusion site within NHS Forth Valley are reported to the Stirling Royal Infirmary (SRI) laboratory and transfusion practitioner by telephone and an incident record form (IR1) is completed. One copy of the IR1 is sent to the unit manager and the second is sent to the risk management department. The clinical risk management co-ordinator receives a copy of all IR1 forms that relate to clinical incidents. If the IR1 relates to blood transfusion, a copy of the form is sent to the transfusion practitioner. Laboratory-based incidents are investigated by the laboratory quality manager with input from the transfusion practitioner and appropriate corrective action taken. The transfusion practitioner investigates all clinical incidents and addresses any training needs with the individuals directly involved in the incident. All blood transfusion-related incidents are discussed by the transfusion practitioner, the clinical lead for transfusion and the laboratory quality manager, and there is further sharing of information about incidents at the transfusion team meetings where recommendations are formulated. The transfusion practitioner prepares an incident report, informs the staff involved, and their manager, and follows up on any outstanding actions or training needs identified.

The hospital transfusion team reports serious blood transfusion related incidents and near miss incidents to Serious Adverse Blood Reactions and Events (SABRE) and Serious Hazards of Transfusion (SHOT). The transfusion practitioner reports on all blood transfusion-related incidents to the HTC, and all SABRE/SHOT reportable events would be discussed at the HTC and the acute services critical incident review group. The review team encouraged the HTC to be more proactive in following up the transfusion practitioner's incident reports and transfusion team recommendations, and modifying protocols to include preventative measures where appropriate.

Standard 1b: Core Principles

Standard Statement

The NHS board has a system in place to ensure that every unit of blood component received into the hospital transfusion laboratory can be unmistakably traced to its recipient, or to its final fate if not transfused.

NHS Forth Valley

Essential Criterion

1b.1: There is a validated system to ensure that evidence of unmistakable traceability is generated, stored and accessible for 30 years.

STATUS: Met

Every unit of blood component received into the SRI blood transfusion laboratory is identified with a donation number. When a component is required for a patient, a paper issue tag is printed from the laboratory computerised system which includes patient identifying information and two self-adhesive traceability labels; each label contains the donation number. The issue tag is attached to the unit of blood component until it is transfused or returned to the laboratory if unused. If transfused, one label from the tag is signed and placed in the patient's notes and the other is completed and returned to the transfusion laboratory to confirm the patient received the component. The returned labels are attached onto the back of an issue sheet with details of components supplied. When reconciled, these issue sheets are stored indefinitely in the laboratory.

If a label is not returned within 1 week of issue of the component, a non-compliance letter is sent to the service manager for the area involved stating which information is missing and asking for confirmation that the units were transfused. The service manager ensures that the area clinical co-ordinator checks the patient's notes and completes the letter. If the letter is returned complete, it is filed with the issue sheet. If the letter is not returned to the laboratory or is returned incomplete, an IR1 form is completed by the medical laboratory assistant (MLA) responsible for monitoring traceability compliance. This letter is sent to the risk management department and the general manager of the area involved. It is then the general manager's responsibility to determine the fate of the units.

The 'bag and tag' system was introduced to NHS Forth Valley at the start of 2007. The transfusion practitioner prepared an instruction sheet for completion of the traceability tags and an illustrated poster on the new system. These were distributed to all relevant areas. It was noted that an action plan is in place to address the findings of a traceability audit which had been conducted by the MLA dedicated to traceability. Staff reported that compliance had improved since the audit and, at the time of the review visit, was running very close to 100%.

Standard 1c: Core Principles

Standard Statement

There is a robust system in place to establish patient identification details and maintain this at every stage of the clinical transfusion process.

NHS Forth Valley

Essential Criteria

1c.1: The minimum identification data set (surname, forename, sex, date of birth and unique identification number, eg Community Health Index [CHI]) is used at every stage of the clinical transfusion process to positively identify the patient.

STATUS: Not met

The NHS Forth Valley blood transfusion protocol states that full name, date of birth, gender and Community Health Index (CHI) or other acceptable unique identifier are used at every stage of the clinical transfusion process to positively identify the patient. A generic patient identification policy has been drafted which includes the same minimum identification data set for inclusion on patient wristbands.

Observational audit of positive patient identification at pre-transfusion sampling, collection and pre-administration identified that the CHI number was not always being recorded and checked, and that gender was not always recorded on wristbands. A separate wristband audit identified that wristbands were not always in place and that the CHI number was not always present. However, phlebotomy staff reported that if a patient was not wearing a wristband, blood would not be taken and action would be taken to ensure that a wristband was prepared for the patient immediately.

Positive patient identification is included in the BBTP training sessions and, following the audit findings, all materials have been updated to include reinforcement of the requirement for completeness of the data set. Further audit is planned.

The review team noted that the policy for venous blood sampling did not refer to gender recording and checking, and encouraged the board to standardise this across all relevant policies.

1c.2: All patients must be identifiable at all times. Inpatients and day patients must wear an identification wristband. If the wristband becomes inaccessible for any reason, an alternative, risk-assessed form of identification is adopted immediately.

STATUS: Not met

The blood transfusion protocol states that all inpatients must wear an identity wristband. The draft patient identification policy applies to inpatients and allows for use of wristbands for day cases. Staff confirmed that blood transfusion would only be conducted if the patient was wearing a wristband.

The draft identification policy is currently being circulated for comment to all interested parties. The draft policy allows for risk-assessed alternatives to be used in such circumstances. At the time of the review visit, however, a risk-assessed alternative was not in use. Staff reported that if, for example, a patient's wristband became covered by drapes in theatre, an identification band would be put on another wrist or ankle if accessible or an addressograph label would be adhered to the patient's forehead. Neither of these options has been risk assessed.

Staff reported that when the identification policy was launched it was intended to issue portable blood audit release system (BARS) scanners to the phlebotomists to pilot their use for identification purposes. A request to include gender in the scanner's software for patient identification checks had been sent to the system provider.

1c.3: There is a system (eg distinctive wristbands) to alert qualified practitioners to patients who have specific transfusion requirements, including the wish to not be transfused.

STATUS: Met

NHS Forth Valley casenotes include a printed divider at the front which has a series of alerts including the existence of an advance directive and specific transfusion requirements. A consent form to operation, investigation or treatment, which includes a section for patients to opt out of receiving a blood transfusion, was being piloted in one specialty prior to roll out across acute services. There is a comprehensive policy for the management of patients who refuse blood transfusion. The review team noted an effective flow chart for the care of women who are pregnant and who refuse the administration of blood or blood products.

For elective surgical patients who refuse transfusion, an information session is arranged with the consultant anaesthetist at their pre-operative assessment.

1c.4: For patients whose identity cannot be confirmed (eg unconscious patients or patients with communication difficulties), a minimum of gender and one unique identifier (eg accident and emergency number or CHI number) is essential for positive patient identification.

STATUS: Met

The blood transfusion protocol states that if an unconscious patient is admitted, and their identity can not be confirmed, a wristband is prepared containing a unique identification number, generated by the accident and emergency information technology (IT) system, and marked with their gender. Staff reported that uniquely numbered identification packs are available in the accident and emergency area for use to identify mass casualties in a major incident. Specific procedures for patients with communication difficulties could not be confirmed by the review team, although it was clear that interpreting and translation facilities were available.

Standard 1d: Core Principles

Standard Statement

The NHS board has a strategy for management of blood shortages.

NHS Forth Valley

Essential Criterion

1d.1: Emergency blood management arrangements (EBMA) are established as defined in HDL(2005)25.

STATUS: Met

An emergency blood stocks management group has been established and is chaired by the NHS Forth Valley medical director. The operational arm of this group is the hospital transfusion team. When the Scottish National Blood Transfusion Service (SNBTS) contacts the SRI transfusion laboratory to advise of a blood shortage, the laboratory contacts the consultant haematologist lead for transfusion who discusses the situation with the medical director. The emergency blood management arrangements (EBMA) and information cascade are activated as appropriate. The review team encouraged the board to consider including all up-to-date contact details within the EBMA flow chart. The EBMA have been linked to the major incident plan and staff reported that, at the most recent clinical governance working group meeting, it had been agreed to test the EBMA in a mock exercise.

Standard 2a: Clinical Management – Pre-Transfusion

Standard Statement

The decision to transfuse is made following consideration of the potential risks and benefits of, and the alternatives to, transfusion. Where possible this is discussed between the clinician and patient (or their legal guardian) in advance of transfusion.

NHS Forth Valley

Essential Criteria

2a.1: The patient's records contain evidence that the reason for transfusion of blood or blood components has been explained and discussed with the patient. This includes discussion of valid alternatives to transfusion and the option to refuse.

STATUS: Not met

An audit of transfusion episode documentation completeness was conducted in the programmed investigation and treatment unit (PITU) at Falkirk & District Royal Infirmary (FDRI). This audit was conducted to measure a baseline against which improvement could be demonstrated following the pilot introduction of a transfusion care pathway for outpatients and day patients in the unit. The audit identified that the reasons for transfusion were being discussed with the patients and documented in their casenotes. There was, however, no documented evidence of a discussion about alternatives to transfusion and the option to refuse. The review team encouraged the HTC to modify the transfusion protocol in line with this standard criterion.

Staff reported that the use of the transfusion care pathway had greatly improved the level of documentation compliance, although this had yet to be formally measured by audit. It was reported that the care pathway had also helped document lines of responsibility for patients who had been referred to the unit by a GP. The pathway was also evaluated in the medical ambulatory care and treatment unit and will be tailored for introduction into other areas across NHS Forth Valley. The review team noted the benefits of introducing the transfusion care pathway and encouraged the board to finalise its implementation in all areas.

2a.2: Leaflets explaining the risks and benefits of, and alternatives to, transfusion are readily available for patients who may require to be, or have been transfused.

STATUS: Met

NHS National Services Scotland produces a variety of blood transfusion-related information leaflets which are available in all relevant areas in NHS Forth Valley. These leaflets are also available in other languages. These are distributed by the transfusion practitioner who maintains records of receipt. A flow chart for contacting interpreters is available in all clinical areas and in the accident and emergency

department there is a phone system which can enable three-way conversation. The new transfusion care pathway contains a prompt to offer a leaflet.

If a patient requests further information on alternatives to transfusion, they are referred to the transfusion practitioner. At the time of the review visit, cell salvage was only available for patients having a revision of a hip replacement. Staff reported that with orthopaedic representation on the HTC, it was anticipated that the awareness of cell salvage might increase.

2a.3: Where pre-transfusion discussion is not possible (eg in an emergency) there is a system, compatible with the patient's clinical needs, to investigate and act in accordance with the patient's treatment preferences. This includes compliance with an advance decision document.

STATUS: Met

Accident and emergency staff confirmed that if an unconscious person was admitted they would search the patient for any identifying information including evidence of the existence of an advance directive. When some identifying features are found, a search on NHSScotland's Emergency Care Summary utility would be made to access further identifying information and any relevant medical details. If there is any indication of the existence of an advance directive, staff would confirm this with any accompanying family or friends before commencing a blood transfusion. These procedures are covered in the scenario induction training for new accident and emergency staff.

There have been no known instances of adverse events or patient complaints arising from non-compliance with advance decision documents.

2a.4: When pre-transfusion discussion has not taken place, the reasons for transfusion (based on risks and benefits) are discussed with the patient and written information offered retrospectively.

STATUS: Not met (insufficient evidence)

Staff reported that women requiring emergency blood transfusion during childbirth would be given an information leaflet prior to discharge. A prompt for issue of an information leaflet is included on the discharge care pathway in use in the intensive care unit and the surgical high dependency unit. Staff reported that they would give the relevant leaflets to attending relatives. Completeness of the discharge care pathway had not been audited and there was no evidence available to the review team to assure it that a post-transfusion discussion was taking place and that information was being offered retrospectively.

Standard 2b: Clinical Management – Pre-Transfusion

Standard Statement

Positive patient identification at the time of sampling and the use of a minimum identification data set on samples and request forms is essential for pre-transfusion testing and blood component requests.

NHS Forth Valley

Essential Criterion

2b.1: Blood samples for transfusion purposes are obtained and labelled in accordance with local protocols, which are based on national guidelines.

STATUS: Not met

Observational audit at the time of pre-transfusion sampling identified that the CHI number was not always being recorded and checked, and that gender was not always recorded on wristbands. A separate wristband audit identified that wristbands were not always in place and that the CHI number was not always present. However, phlebotomy staff reported that if a patient was not wearing a wristband, blood would not be taken and action would be taken to ensure that a wristband was prepared for the patient immediately. Such instances would be reported to the transfusion practitioner who would follow up with the staff involved and provide additional training if necessary. It was reported that there was no single area where this error occurred more frequently than in any other.

The audit also demonstrated that sample tubes were being handwritten, the majority at the patient's bedside as per local protocols.

The SRI laboratory standard operating procedure for receipt and labelling of transfusion requires a check that the full name, date of birth and CHI number on the sample match those on the request form, however, a check on gender is not included. When a sample is not adequately labelled, or there is a discrepancy between the sample and the request form, a sample error log book is completed by laboratory staff. Minor amendments can be rectified and an amendment form completed and attached to the request form, otherwise a fresh sample is requested. If any one person is identified as persistently making errors then the transfusion practitioner would be informed and retraining organised.

If mislabelled samples are received from GPs for patients who will be attending the PITU, these would be rejected and fresh samples requested. Staff reported that such instances are noted on the laboratory error log and staff now also complete an IR1 form. Such incidents would be reported back to the relevant community health partnership and the review team highlighted this as a strong clinical governance link.

Standard 2c: Clinical Management – Pre-Transfusion

Standard Statement

Blood and blood component prescribing is the responsibility of a qualified practitioner.

NHS Forth Valley

Essential Criteria

2c.1: All prescriptions for blood and blood components are signed by a qualified practitioner.

STATUS: Met

There is space for the signature of a qualified practitioner on the intravenous fluid prescription chart which is in use throughout NHS Forth Valley. The transfusion care pathway which has been piloted has space for the prescriber's signature.

The documentation audit conducted within the PITU demonstrated that all prescriptions were being signed by a qualified practitioner.

2c.2: Blood and blood component prescriptions specify: blood component to be administered; number of units (millilitres in paediatric patients) to be transfused; duration of transfusion; any special requirement, and any special instructions.

STATUS: Met

Blood and blood component prescriptions specify blood component to be administered, number of units, duration of transfusion and any special requirements and instructions as per the blood transfusion protocol. There are separate transfusion guidelines for neonates and children less than 1 year old which require the prescription to specify volume of blood in millilitres. Special requirements would be entered on the laboratory computer system and would be flagged up each time a unit was requested. There is also a prompt for special requirements and instructions on the new transfusion care pathway.

The documentation audit found that prescriptions complied with the requirements of this standard criterion.

Standard 3a: Clinical Management – Hospital Transfusion Laboratory

Standard Statement

Laboratory operations comply with current regulatory requirements.

NHS Forth Valley

Essential Criteria

3a.1: All transfusion laboratories within the NHS board are accredited by Clinical Pathology Accreditation (UK) Ltd (CPA) or equivalent and are compliant with the Medicines and Healthcare products Regulatory Agency (MHRA) requirements.

STATUS: Not met

The departments of haematology and blood transfusion at FDRI and SRI are accredited by Clinical Pathology Accreditation (UK) Ltd (CPA) and will be re-assessed in May 2008. The SRI hospital blood bank is scheduled for inspection by the Medicines and Healthcare products Regulatory Agency (MHRA) in the first quarter of 2008. A mock inspection has been carried out and a detailed action plan to address the findings is being actively followed through with appropriate resources identified.

A service level agreement is in place between NHS Forth Valley and Strathcarron Hospice, Denny, to secure the provision of blood components and related services to a level that satisfies the requirements of the Blood Safety and Quality Regulations 2005. Blood and blood components are supplied to Strathcarron Hospice by the SRI blood bank on a named patient basis and the hospice follows the NHS Forth Valley protocols for blood transfusion. Hospice staff are included in the BBTP training provided by the NHS Forth Valley transfusion practitioner.

NHS Forth Valley commissions services for NHS patients from Abbey King's Park Hospital, Stirling. At the time of the review visit, a service level agreement had been drafted to assure that these services are compliant with all standards of care (and subsequent updates) as set by both the Care Commission and NHS Quality Improvement Scotland (NHS QIS). The review team encouraged the board to finalise this agreement and to assure themselves that the BBTP training was ongoing in Abbey King's Park Hospital. The review team also encouraged the sharing of transfusion-related documentation including the new transfusion care pathway. The laboratory in Abbey King's Park Hospital is compliant with MHRA requirements.

3a.2: Competency-based training and assessment systems are in place and training records are maintained.

STATUS: Met

The mock MHRA inspection identified the need for the implementation of competency-based training and assessment systems and the maintenance of training records. Since the mock inspection, all biomedical scientists working in the blood transfusion laboratory had prepared and completed a competency log and personal training folders were in use. The review team acknowledged this considerable achievement.

Standard 3b: Clinical Management – Hospital Transfusion Laboratory

Standard Statement

Procedures are in place to optimise blood use and minimise wastage.

NHS Forth Valley

Essential Criteria

3b.1: Protocols endorsed by the HTC are in place, including but not limited to: the maximum surgical blood ordering schedule (MSBOS); massive blood loss; major incidents; and emergency blood management arrangements.

STATUS: Met

The maximum surgical blood ordering schedule (MSBOS) followed at SRI and FDRI is included in the NHS Forth Valley blood transfusion protocol which has been endorsed by the HTC. The review team encouraged the board to consider auditing compliance with this schedule.

The review team commended the protocols for massive haemorrhage in use at SRI and FDRI. Staff reported that mock exercises to test the protocols had taken place and the findings were fed back to the HTC which led to an improved protocol.

The review team encouraged the board to consider incorporating the blood transfusion laboratory procedures for response to major incidents into the existing major incident protocol. The EBMA were considered satisfactory.

The laboratory receives a monthly summary of blood component transactions from SNBTS which is discussed at the hospital transfusion team meetings and at the HTC. It has only recently become possible for the laboratory to track its own wastage rates to various departments, and staff reported that these wastage rates would be monitored by the HTC in the future.

3b.2: There is a stock management system to eliminate excess inventory and reduce waste, supported by an information technology (IT) system.

STATUS: Not met

At the time of the review visit, a paper-based blood stock management system was in use, although it was scheduled to be replaced by a more robust IT system which had already been purchased (Blood Track®). The review team noted that the implementation of the Blood Track® system and the associated training programme would present a significant challenge for the board, although implementation would enable more efficient stock management and closer monitoring of blood wastage rates. This would lead to the laboratory being in a position to contribute to the BBTP Scottish Transfusion Epidemiology Database.

Standard operating procedures are in place for the emergency issue of O RhD negative blood units and blood stock levels are monitored so that optimal blood usage is achieved and as little as possible wasted by going out of date. At the time of the review visit, there was an MLA dedicated to monitoring the traceability process for the receipt, movement and storage of blood components.

3b.3: In collaboration with clinical specialties, laboratory staff participate in audit of transfusion issues.

STATUS: Not met

The board has identified that there is limited audit collaboration between laboratory staff and clinical specialties. This was highlighted by the mock MHRA inspection and has been addressed in the action plan. Traceability compliance data are collected on an ongoing basis, however, the review team encouraged the board to consider incorporating other regular audits into routine laboratory practice, in collaboration with clinical specialties. It was reported that the recently extended membership of the HTC was anticipated to encourage collaborative audit activity and that additional audit resource was being recruited into the laboratory at SRI.

Standard 4a: Clinical Management – Blood and Blood Component Collection, Administration and Monitoring

Standard Statement

Positive patient identification is performed against the blood component and any accompanying documentation at every stage of the clinical transfusion process.

NHS Forth Valley

Essential Criteria

4a.1: Only staff who have completed the BBTP continuing education programme (or equivalent) appropriate to their role can participate in the clinical transfusion process.

STATUS: Not met

The NHS Forth Valley blood transfusion protocol states that only medical and nursing/midwifery staff, who have completed BBTP education appropriate to their role, can take part in the transfusion process. The training has to be updated every 2 years.

The transfusion practitioner maintains a database which details levels of training received by all staff involved in the clinical transfusion process and is advised when new staff join NHS Forth Valley. The transfusion practitioner delivers induction training for foundation year one (FY1) doctors, registered nurses, midwives, operating department practitioners and nursing auxiliaries. Face-to-face sessions have been conducted for all staff groups involved with the blood transfusion process including senior house officers in accident and emergency, theatre and obstetrics and gynaecology. Some consultant anaesthetists and consultants from obstetrics and gynaecology have also attended the face-to-face sessions, however, within this staff group, the percentage trained is too low to ensure that only BBTP trained staff participate in the transfusion process. Over 90% of nursing staff have received BBTP Level 1: Safe Transfusion Practice training. All phlebotomists have received training in taking a pre-transfusion blood sample. There is a porter dedicated to blood collection and other porters who might be involved have also received BBTP Level 1 training. There are five other BBTP trainers: in the surgical unit; accident and emergency; intensive care area; theatre; and in the renal unit.

At the face-to-face sessions, staff are encouraged to utilise the Better Blood Transfusion Continuing Education Programme elearning materials which can be accessed through the OrasGold™ online recording and assessment system. OrasGold™ can be accessed by staff who work night shifts and FY1 doctors have to complete Level 1 and 2 training using OrasGold™ within their first 2 months of commencing in NHS Forth Valley. The postgraduate tutor can check if the FY1s have completed the required modules by accessing the NHSScotland Doctors Online Training System (DOTS). It was reported that retraining after 2 years was planned

for all staff groups. Training for some staff groups such as porters will continue to be face-to-face, although the majority will be using OrasGold™.

The lead clinician for blood transfusion delivers induction training to the foundation year two doctors and is promoting the completion of BBTP Level 1 training using OrasGold™ to all senior medical staff. The lead clinician is being assisted with this by the NHS Forth Valley medical director and a proposal to include a check that this has been completed at annual appraisal is under consideration.

Participation in the SNBTS Trainers and Assessors Accreditation Programme is under way and NHS Forth Valley will participate in a pilot of a competency-based assessment tool for the collection of blood and blood components in early 2008.

The percentage of BBTP trained staff, with the exception of the senior medical staff, is very high and was commended by the review team.

4a.2: The minimum identification data set is recorded on all transfusion documentation (see standard criterion 1c.1).

STATUS: Not met

The NHS Forth Valley blood transfusion protocol requires the minimum identification data set (full name, date of birth, gender and CHI or other acceptable unique identifier) to be used on all transfusion-related documentation. Observational audit has, however, shown that wristbands do not always include the CHI number or patient gender.

Standard 4b: Clinical Management – Blood and Blood Component Collection, Administration and Monitoring

Standard Statement

Patients are monitored for any adverse events or reactions during and after the transfusion process as clinically indicated.

NHS Forth Valley

Essential Criteria

4b.1: Patients are monitored according to hospital transfusion policy and any untoward events (including suspected adverse reactions) are immediately clinically managed and promptly reported to the HTL.

STATUS: Not met

The NHS Forth Valley blood transfusion protocol states that baseline recording of temperature, pulse, respirations and blood pressure should be done before the start of transfusion of each unit. Temperature and pulse should then be measured and recorded at 15 and 30 minutes after the start of the transfusion and hourly thereafter until the end of the transfusion episode. The new transfusion pathway specifies the same baseline set of observations as the protocol, however, the pathway states that respirations must be recorded 15 and 30 minutes after the start of transfusion, in addition to temperature and pulse.

Observational audit of transfusion episodes indicated that the blood transfusion protocol was not always being followed, and that temperature and pulse were not always being monitored pre-transfusion. Documentation audit also found that the monitoring observations were not always being documented in accordance with the protocol.

Staff confirmed that flow charts for the management of severe acute reactions are clearly displayed in all clinical areas and include a step to promptly report these reactions to the hospital laboratory.

4b.2: Serious adverse events and near miss incidents are reported on the clinical incident reporting system in accordance with local protocols.

STATUS: Met

The review team noted the clarity of the posters notifying staff that serious adverse blood events and serious adverse blood reactions should be recorded on an IR1 as well as by telephone to the transfusion practitioner. There was clear documentation to support the process of reporting adverse events and near miss incidents in accordance with local protocols. The transfusion practitioner follows up investigations with individuals involved and delivers additional training if required.

The transfusion practitioner also reports the outcome of the investigations to managers or educational supervisors.

4b.3: Reports of serious adverse events or reactions and near miss incidents are submitted to Serious Adverse Blood Reactions and Events (SABRE) and the Serious Hazards of Transfusion (SHOT) initiative by the relevant staff.

STATUS: Met

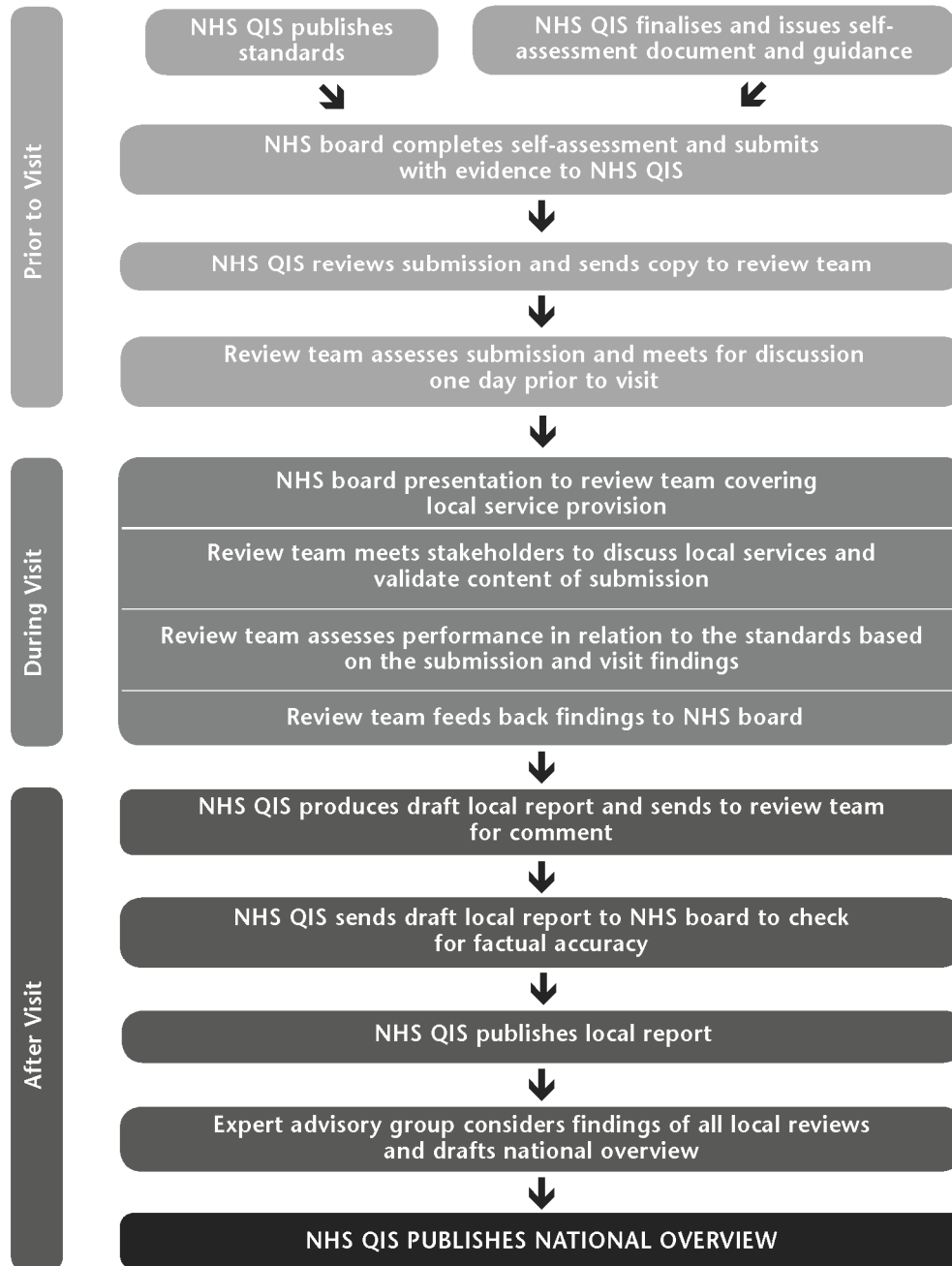
There is an NHS Forth Valley SABRE reporting group which includes the lead clinician for transfusion, the transfusion practitioner, the blood bank manager, laboratory manager and a biomedical scientist. Each member of the group has password protected access to report to the SHOT initiative via the SABRE reporting system.

Appendix 1 – Glossary of abbreviations

Abbreviation

BARS	blood audit release system
BBTP	Better Blood Transfusion Programme
CGC	clinical governance committee
CHI	Community Health Index
CPA	Clinical Pathology Accreditation (UK) Ltd
DOTS	Doctors Online Training System
EBMA	emergency blood management arrangements
FDRI	Falkirk & District Royal Infirmary
FY1	foundation year one
GP	general practitioner
HTC	hospital transfusion committee
IT	information technology
MHRA	Medicines and Healthcare products Regulatory Agency
MLA	medical laboratory assistant
MSBOS	maximum surgical blood ordering schedule
NHS QIS	NHS Quality Improvement Scotland
PITU	programmed investigation and treatment unit
SABRE	Serious Adverse Blood Reactions
SHOT	Serious Hazards of Transfusion
SNBTS	Scottish National Blood Transfusion Service
SRI	Stirling Royal Infirmary
WOSBTS	West of Scotland Blood Transfusion Service

Appendix 2 – Review process



Appendix 3 – Details of review visit

The review visit to NHS Forth Valley was conducted on 6 February 2008.

Review team members

Dr Fiona Scott (Team Leader)

Consultant Haematologist, NHS Lothian

Ms Patricia Bryson

Public Partner, Greater Glasgow and Clyde

Ms Wendy McGeoghie

Midwifery Team Leader, NHS Tayside

Mrs Kay Pearson

Blood Bank Manager, NHS Greater Glasgow and Clyde

Ms Pauline Stewart

Transfusion Practitioner, NHS Lanarkshire

Dr Steve Cross

Senior Consultant, Human Reliability (Observer)

NHS Quality Improvement Scotland Staff

Ms Nanisa Feilden

Senior Project Officer

Dr Avril MacLennan

Project Officer

Miss Fiona McCrystal

Project Administrator (Observer)

During the visit, members of the review team met with consultant and nursing staff, transfusion laboratory staff, transfusion practitioners and support staff from across the NHS board area.

The composition of each team varies, and members have no connection with the NHS board they are reviewing. Both of these factors facilitate the sharing of good practice across NHSScotland, and ensure that each review team assesses performance against the standards rather than make comparisons between one NHS board and another. The team remit does not include reviewing the work of individual healthcare professionals, variations in practice (and potential quality) within a service will be encountered and subsequently reported.

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NHS Quality Improvement Scotland

Edinburgh Office
Elliott House
8-10 Hillside Crescent
Edinburgh EH7 5EA

Phone: 0131 623 4300
Textphone: 0131 623 4383

Email: comments@nhshealthquality.org
Website: www.nhshealthquality.org

Glasgow Office
Delta House
50 West Nile Street
Glasgow G1 2NP

Phone: 0141 225 6999
Textphone: 0141 241 6316