

NHS Lothian

Local Report ~ *February 2008*

Blood Transfusion

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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 Lothian'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 flowchart 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 Lothian** on **6 September 2007** can be found in Appendix 3.

2 Summary of findings

2.1 Overview of local service provision

Lothian is situated in south-east Scotland and has a population of around 801,310¹. The majority of the population live in densely populated urban areas, of which Edinburgh followed by Livingston is the largest in the region.

Local NHS system and services

Lothian 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 Lothian.

At the time of the review visit, NHS Lothian provided acute and specialist services through three operating divisions, the Lothian University Hospitals Division (LUHD), the division comprising Royal Edinburgh and Associated Services/Mental Health Services and the primary care and community hospitals division. The latter includes three community health partnerships and one community health care partnership.

Further information about the local NHS system can be accessed via the website of NHS Lothian (www.nhslothian.scot.nhs.uk).

There are three NHS hospital blood banks within NHS Lothian; at the Western General Hospital (WGH), Edinburgh, at St John's Hospital, Livingston, and the Edinburgh & South East Scotland SNBTS (Clinical Directorate) hospital transfusion laboratory (SEBTS), based at the Royal Infirmary of Edinburgh (RIE). There is also a blood bank at BUPA Murrayfield Hospital, Edinburgh.

SEBTS supplies WGH, St John's Hospital and BUPA Murrayfield blood banks with blood and blood components. The blood bank at the WGH supplies blood and blood components to the Royal Victoria Hospital, Edinburgh. The SEBTS blood bank also supplies blood and blood components to: the RIE; the Royal Hospital for Sick Children (RHSC), Edinburgh; Roodlands Hospital, Haddington; Liberton Hospital, Edinburgh, St Columba's and Marie Curie Hospices and community hospitals.

In the 12 months prior to the review visit, approximately 41,500 red cell units, 11,500 plasma units and 9,000 platelet units were transfused in NHS Lothian. The majority of those units were used at the RIE for surgery, obstetrics and in the trauma unit. Units used at the WGH were primarily used for haematology and oncology services as well as in the bone marrow transplantation unit. There was also a significant usage at St John's Hospital in the plastics and burns unit as well as for obstetrics.

The NHSScotland Better Blood Transfusion Programme (BBTP) is supported in NHS Lothian by two transfusion practitioners who work across all sites where blood transfusion takes place within NHS Lothian. These are further assisted by a network of local 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 Lothian has a hospital transfusion committee (HTC) that was established in 2000 and is accountable to the University Hospitals Division clinical governance and risk management committee. The HTC meets quarterly and is chaired by a consultant anaesthetist. The committee is responsible for ensuring that blood bank and transfusion policies and activities, as well as the use of blood components are safe and effectively managed. In addition to the NHS Lothian HTC, there are separate HTCs at the WGH and St John's Hospital. However, at the time of the visit the relationship between the HTCs and the current reporting structure was unclear. The review team encouraged the board to extend the NHS Lothian HTC membership to include representation from all hospitals and appropriate health professions across the NHS board area.

There was evidence of appropriate blood transfusion practice audit activity in all areas across the board with identified funding to support audit projects. There was also wide dissemination of audit data to relevant staff groups in a variety of formats and evidence of changes in practice as a result of outcome was observed.

The HTC is actively involved in encouraging and approving training programmes for multidisciplinary staff working in the hospital blood transfusion service. However, the endorsement and harmonisation of blood transfusion protocols and procedures for use throughout NHS Lothian was noted to be a challenge for the board.

There are procedures in place for the recording and reporting of critical incidents within NHS Lothian, and these incidents are monitored and investigated. All serious adverse events and near miss incidents relating to blood transfusion practice within NHS Lothian are submitted and reviewed by Serious Adverse Blood Reactions and Events (SABRE) and the Serious Hazards of Transfusion (SHOT) initiative. All incidents are reviewed by the clinical management team of the area where the incident took place and considered by the transfusion team on each site.

NHS Lothian use a 'bag and tag' system to ensure every unit of blood component received into the laboratory can be traced to its recipient or to its final fate if not transfused.

All staff engaged in the blood transfusion process within NHS Lothian are trained to establish and maintain patient identification details at every stage of the blood transfusion process. A recent audit of the identification procedures used in relation to the minimum data set did, however, identify limited compliance. A newly revised draft identification policy document was available at the time of the visit. The review team encouraged the board to implement standardisation throughout NHS Lothian through use of this document which also needs to include identification procedures for children aged less than one year.

Clinical management – pre-transfusion

The review team was informed that there is a system in place to discuss with patients treatment options and alternatives to transfusion. However, an audit of recorded documentation found poor compliance with this procedure, although it was noted that this is currently being addressed for improvement by the board. Retrospective discussion with patients who did not have a pre-transfusion discussion does not currently take place.

There is a wide range of leaflets and information available for patients explaining the risks and benefits of blood transfusion and the alternatives available in various formats. The review team noted a co-ordinated approach towards the supply and distribution of patient information leaflets.

Staff recognise and respect the individual choice of patients regarding treatment options. In emergency situations, effort is made to identify if an advance statement about an individual's medical treatment preference exists by searching the hospital notes and contacting identified people known to the patient. However, emergency treatment would not be delayed in order to look for an advance statement if there is no indication that one exists. There is a good working relationship between the transfusion service and the Edinburgh Hospital Liaison Committee for Jehovah's Witnesses.

It is routine practice across NHS Lothian that blood and blood component prescribing is signed by a qualified practitioner.

Clinical management – hospital transfusion laboratory

All transfusion laboratories within NHS Lothian are accredited by the Clinical Pathology Accreditation (UK) Ltd (CPA) and are compliant with the requirements of the Medicines and Healthcare products Regulatory Agency (MHRA).

There are procedures in place to optimise blood use and minimise wastage. At the time of the visit, it was noted that NHS Lothian is actively moving towards introducing a single system for the maximum surgical blood ordering schedule at the RIE, WGH and St John's Hospital. Blood wastage rates are monitored and reported in all areas.

Blood stock management and emergency protocols for the use of O negative blood are in place and supported by information technology systems. The review team encouraged the board to consider specifying the locations of the various blood fridges available within NHS Lothian hospitals in the transfusion policy to support emergency blood supplies being quickly accessible.

The review team acknowledged the close working relationship between the laboratories and transfusion practitioners.

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

There was good evidence of theoretical competency-based training being delivered to a wide range of staff providing hospital blood transfusion. Training is monitored. However, engaging senior medical staff to attend competency-based training was recognised as a challenge by the board and this is being addressed. The review team noted as a strength of the service the amount of theoretical training completed by some staff groups.

Recording the minimum data set requirements on all transfusion documents is a challenge for the board and this is being actioned by the HTC.

Patients receiving a blood transfusion have observations of temperature, pulse and blood pressure recorded throughout the duration of the transfusion and for a period of time post transfusion to support identification of any adverse reactions. A fluid balance chart is also maintained. There are clear escalation procedures in place for staff to follow should observations during transfusion give any indication of concern. However, an audit of compliance with observation recordings found not all documents contained transfusion monitoring and this is being addressed by the HTC.

There are robust SHOT and SABRE reporting systems in place with mechanisms to provide feedback on lessons learned to staff.

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 Lothian

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: Not met

The NHS Lothian hospital transfusion committee (HTC), based at the Royal Infirmary of Edinburgh (RIE) was established in 2000 as an overarching committee replacing separate transfusion committees based at RIE and the Western General Hospital (WGH), Edinburgh. The committee meets quarterly and is chaired by a consultant anaesthetist. The NHS Lothian HTC reports to the NHS Lothian University Hospitals Division (LUHD) clinical governance and risk management committee. This committee reports to the NHS Lothian healthcare governance and risk management committee which reports directly to NHS Lothian board. However, separate HTCs exist at the WGH and St John's Hospital, Livingston, which are subcommittees of the NHS Lothian HTC.

The NHS Lothian HTC has a clearly defined, documented remit which outlines its roles and responsibilities as specified in MEL(1999)9. The review team found, however, that the documented constitution of the overarching HTC was not prescriptive enough in terms of the breadth of its multidisciplinary membership and that certain key sites and roles were not represented in the current membership. The review team recognised that there were some existing vacancies on the NHS Lothian HTC. Although the Royal Hospital for Sick Children (RHSC), Edinburgh, was currently represented on the HTC by one of the transfusion practitioners, consideration should be given to having specific representation from RHSC. The review team noted as a challenge for the board the need to prioritise recruiting to the HTC vacancies and extending the membership to include representation from Liberton Hospital, Edinburgh, Royal Victoria Hospital, Edinburgh, community hospitals and nursing, neonatology and paediatric specialties.

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

Audit activity is led by quality improvement teams that receive proposals for audit topics from various departments. The review team found evidence of considerable audit activity related to blood transfusion and there is specific funding for audit related to the Better Blood Transfusion Programme (BBTP). The review team did, however, find evidence of adequate involvement of the HTC in audit activity. Audit data are disseminated widely to relevant staff groups using a variety of presentation methods and improvement in clinical practices related to blood transfusion was demonstrated.

Education and training in blood transfusion is a standing item on the HTC agenda and regular updates are prepared for the HTC by the transfusion practitioners. Training agreements for foundation year one doctors, foundation year two doctors, senior house officers, nursing and midwifery staff, operating department practitioners and phlebotomists have been approved by the HTC.

The NHS Lothian HTC was involved in a review of the LUHD blood components clinical procedures manual in 2006 and the manual is available on the NHS Lothian intranet. Separate and different blood transfusion guidelines are in use at St John's Hospital and the RIE neonatal unit. The review team considered this to reflect that the NHS Lothian HTC did not have the level of authority to introduce the most appropriate changes to blood transfusion practice throughout NHS Lothian, as defined in MEL(1999)9. Staff reported that a document control policy, ratified by the NHS Lothian board in 2006, will support standardisation of guidelines and protocols across NHS Lothian. At the time of the review visit, this policy had yet to be fully implemented.

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

STATUS: Met

NHS Lothian transfusion practitioners meet regularly with the BBTP lead clinician for the LUHD. Meetings are also held between the relevant transfusion practitioner and nominated clinical leads for the programme in WGH, RHSC and St John's Hospital.

There is a nominated clinical lead for the education programme for nursing, medical and other relevant allied health professional staff and a clinical lead for peri-operative blood conservation. All these clinical leads are members of the NHS Lothian HTC

and the BBTP is a standing agenda item. The review team found good evidence of HTC and quality improvement team support for the BBTP targets.

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: Met

Adverse events and near miss incidents relating to blood transfusion which occur in clinical areas of NHS Lothian are entered into DATIX (a computerised risk management reporting system) by the relevant clinician. The transfusion practitioners also enter data on incident reports received from Edinburgh & South East Scotland Blood Transfusion Service (SEBTS) quality assurance (QA) staff. The practitioners investigate the incidents and report findings, actions taken and recommendations for changes in practice to the laboratory quality manager, risk management facilitator, LUHD as well as to SEBTS QA staff. Reports of serious adverse events or reactions and near miss incidents are also submitted to Serious Adverse Blood Reactions and Events (SABRE) and the Serious Hazards of Transfusion (SHOT) initiative.

Serious near miss events and all SABRE and SHOT reportable incidents are reviewed by the NHS Lothian HTC.

The transfusion practitioners and SEBTS QA staff feedback the outcome of incidents/near misses to clinical and blood bank staff through presentations, email alerts and incorporation into education for all staff groups. The transfusion practitioners share information on lessons learned with transfusion practitioners from other NHS boards at their regular teleconferences, educational conferences, BBTP forum meetings and via SHOT.

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 Lothian

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 blood transfusion laboratories within NHS Lothian is identified with a donation number. When a component is required for a patient, a paper tag is printed from the laboratory computerised system which includes patient identifying information and two traceability labels, each label contains the donation number. Staff reported that the tag always accompanies 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 hospital transfusion laboratory to confirm the patient received the component. The data from the returned labels is entered into the computerised system that records the fate of each component. Paper copies of the returned labels are held in the laboratory until permanently archived.

This 'bag and tag' system has been in place in NHS Lothian since mid-2006 and instances of non-returned labels are monitored and corrective action taken. Audit of placement of the label in the patient notes has identified inconsistency of approach and there are slightly different systems for recording fate and follow-up of non-returned labels in each hospital transfusion laboratory. The review team recognised the staff efforts to achieve traceability compliance across all sites and encouraged the board to consider standardising procedures across NHS Lothian.

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 Lothian

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

At the time of the visit, the review team noted that there were variable identification policies in use across NHS Lothian and an audit of the minimum data set found that there was minimal compliance with this criterion. In addition, staff reported that the admission computer system in place at St John's Hospital does not allow for the minimum identification data set to be generated for all patients. This has been recognised and staff reported that the St John's Hospital system will be rectified by the introduction of a new NHS Lothian identification policy which was available in draft format at the time of the review visit.

The review team encouraged the board to standardise systems across NHS Lothian and to continue to audit compliance to ensure that the minimum data set is used at every stage of the clinical transfusion process. The revised identification policy should also include identification procedures for children aged less than one year old.

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

Staff are trained to ensure that all inpatients who have pre-transfusion blood samples taken and all patients receiving a blood transfusion wear a wristband. Outpatients scheduled to receive a blood transfusion also wear a wristband. Patients attending pre-operative clinics do not wear wristbands.

If the wristband becomes inaccessible for any reason, there is no risk-assessed form of identification adopted. Staff reported that in theatre, if the wristband is likely to be covered by drapes, the wristband would be removed and tied around the tracheal tube or taped onto the patient's forehead, according to individual consultant preference. The review team encouraged the NHS Lothian HTC to include a risk-assessed alternative to identity bands in the newly drafted identification policy.

Staff are trained to ensure that the wristband details are positively confirmed by the patient prior to taking blood samples and that the details match the request form. Data from the wristband are then copied to the sample tube.

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: Not met

Staff informed the review team that any special transfusion requirements, including the wishes of patients who did not want to be transfused, would be written in the patient's notes. However, at the time of the review visit there was no formal method of distinct identification in place for such patients. Patients with allergies are currently identified with a coloured wristband and staff reported that this was being considered for the identification of those patients who did not consent to transfusion. The board recognised that a more robust alert system should be approved by the NHS Lothian HTC and included in the newly drafted identification policy.

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

NHS Lothian has a documented system in place for wristband completion for patients who are unable to positively identify themselves. For unconscious patients, two staff members check and confirm the identity of the patient from the wristband which contains gender and an accident and emergency number.

Standard 1d: Core Principles

Standard Statement

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

NHS Lothian

Essential Criterion

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

STATUS: Met

NHS Lothian has established an emergency blood management group which has executive powers on behalf of the chief executive for NHS Lothian. The documented emergency blood management arrangements (EBMA) would be activated when the nominated consultant with responsibility for transfusion is notified of a blood shortage by the Scottish National Blood Transfusion Service (SNBTS). The arrangement is based on HDL(2005)25, however, the review team advised that the specific responsibilities of key individuals involved in the activation and conduct of EBMA should be clarified.

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 Lothian

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

The review team acknowledged the difficulties in meeting this criterion, however, an interim report of a small retrospective blood transfusion identification audit undertaken in June 2007 found that not all case notes had documented evidence of recorded discussions regarding the transfusion, alternatives available and refusals. Staff are aware of the need to document the reason for transfusion, the discussion with the patient and the patient's consent. The review team was informed that staff compliance with document recording is currently being addressed.

Consent forms which include information on alternatives to transfusion and the option to refuse transfusion are readily available in all areas. Staff reported that consent forms for refusal of transfusion are available for all patients. There is a documented policy on obtaining informed consent within NHS Lothian and consent to transfusion is also referenced in the transfusion guidelines.

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

There is a well co-ordinated, structured approach to the supply and distribution of national patient information leaflets: Receiving a Transfusion: Information for Patients and Relatives; Red Cell Transfusion: Information for Doctors and Nurses; and Preventing Rhesus Disease in Your Baby: Information for Pregnant Women with Rhesus Negative Blood. Leaflets are available on the NHS Lothian intranet and hard copies are held in each clinical area. Copies of these leaflets are sourced from NHS National Services Scotland and the publications are available from them in large print, Braille (English only), audio tape and in different languages.

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

The review team was informed that if a patient had refused a transfusion, this would be recorded in the hospital notes which are consulted prior to transfusion. Where immediate patient care requires a transfusion and there is not time for a full discussion, measures are taken to try and establish if an advance decision document exists, eg accident and emergency staff would search the patient and their personal effects and ask accompanying family or friends. Staff reported that no adverse events or patient complaints about non compliance with their transfusion treatment preferences are known to have been received by the board. The review team noted the good working relationship between the transfusion service and the Edinburgh Hospital Liaison Committee for Jehovah's Witnesses which includes representatives from across the NHS Lothian region.

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

When pre-transfusion discussion has not taken place, there is no specific discussion with the patient about the transfusion. The review team encouraged the board to include a retrospective discussion in their transfusion policy.

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 Lothian

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

Blood samples for transfusion purposes are labelled in accordance with either the St John's Hospital transfusion guidelines, the LUHD blood components clinical procedures manual or the SEBTC laboratory handbook. However, at the time of the visit, St John's Hospital was unable to comply with the recording of the minimum identification data set on blood samples. The review team recognised that work is being undertaken by the board to address this issue which will be resolved following approval and implementation of the newly drafted patient identification policy.

Standard 2c: Clinical Management – Pre-Transfusion

Standard Statement

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

NHS Lothian

Essential Criteria

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

STATUS: Met

Prescriptions for blood and blood components are routinely signed by a qualified practitioner. This signatory is not always identifiable unless the practitioner's name is printed alongside. An audit on identification data recently highlighted this and the transfusion practitioners are progressing the suggestion of using a name stamp as well as signature.

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 requirements; and any special instructions.

STATUS: Not met

The review team noted that the blood transfusion identification audit found a significant number of prescriptions which were not completed fully. While the blood component to be administered was recorded in nearly all cases, the duration of transfusion was not always specified. It was also noted that the document used to record the prescription was not standardised and did not include prompt boxes for special requirements such as irradiated units. The review team encouraged the board to progress the standardisation of protocols and procedures across NHS Lothian which would address some of the audit findings. It was further noted that the continuing education programmes being managed by the transfusion practitioners would also address some of the findings.

Standard 3a: Clinical Management – Hospital Transfusion Laboratory

Standard Statement

Laboratory operations comply with current regulatory requirements.

NHS Lothian

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: Met

At the time of the review visit, the transfusion laboratory staff in the WGH had taken action to address three ‘critical non-compliances’ following an inspection by personnel from Clinical Pathology Accreditation (UK) Ltd (CPA) and the laboratory was due to be re-inspected in October 2007. The WGH laboratory currently has conditional approval status from the CPA and is certificated as compliant with the Medicines and Healthcare products Regulatory Agency (MHRA).

The transfusion laboratory at St John’s Hospital has been accredited by the CPA and has evidence of compliance with MHRA requirements.

The SEBTC laboratory in RIE also has been accredited by the CPA and is compliant with MHRA requirements. A CPA inspection took place there recently and the CPA report is awaited.

NHS Lothian commissions services for NHS patients from BUPA Hospitals Ltd (Murrayfield Hospital, Edinburgh) and has a service level agreement in place 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. A team of NHS Lothian staff has conducted quality assurance visits to BUPA Murrayfield Hospital and the blood bank there has conditional CPA approval status and a general compliance certificate from the MHRA. BUPA Murrayfield Hospital has an HTC and its action plan for progressing the BBTP has been submitted to the NHS Lothian HTC.

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

STATUS: Met

Training programmes for laboratory staff are in use at each of the hospital transfusion laboratories and individual training records including assessment are held in each laboratory. The divisional training manager has been tasked with ensuring that all transfusion laboratory staff receive competency-based training and assessment in line with CPA requirements.

Standard 3b: Clinical Management – Hospital Transfusion Laboratory

Standard Statement

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

NHS Lothian

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: Not met (insufficient evidence)

There was limited evidence of the HTC process for endorsing protocols (see standard criterion 1a.2). However, staff reported that, at the time of the review visit, NHS Lothian HTC was working on unifying the maximum surgical blood ordering schedule across Lothian hospitals.

Protocols for managing major haemorrhage are in place in RIE, WGH and St John's Hospital. Transfusion laboratory staff accept a call from a clinician to invoke this protocol. Staff reported that locally it had been agreed not to include a definition of major haemorrhage in their protocol. The review team could not ascertain the protocol used by staff at the RHSC for managing massive blood loss, although it was noted that two mock exercises had been conducted to test the RHSC protocol. The review team encouraged the board to consider harmonising these protocols while still allowing for local differences which have been developed to optimise blood use and reduce wastage.

Major incident protocols are available in all relevant hospital and laboratory areas and EBMA are available on the NHS Lothian intranet, however, the review team advised that the specific responsibilities of key individuals involved in the activation and conduct of EBMA should be clarified.

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

STATUS: Met

All blood banks in NHS Lothian have stock management systems in place and there are protocols for the emergency issue of O RhD negative red cells. Only the SEBTC has O RhD negative units stored outside the blood bank and these units are held in the RIE accident & emergency department and in the obstetric theatre. One unit is also held at RHSC. There is a protocol in place to ensure that SEBTC staff are notified when any of the units held in peripheral fridges are used and need to be

replenished. SEBTC staff also conduct daily checks on the peripheral fridges and contents. The review team encouraged the HTC to consider modifying the LUHD blood components clinical procedures manual and/or the massive blood loss protocol to specify the location of peripheral fridges.

Information technology systems are in place which support the blood stock management system and staff reported that it is planned to introduce the WGH APEX system into St John's Hospital to harmonise information held on stocks and eliminate excess inventory. At the time of the review visit, it was reported that the frequency of expiring blood component stock enquiries at WGH and St John's Hospital was to be increased from weekly to daily. The SEBTC blood bank within RIE operates its own stock management system which will be updated to Traceline as part of the NHS National Services Scotland corporate business plan (2007/2008).

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

STATUS: Met

The transfusion practitioners take the lead with clinical audit of the transfusion process and share findings with laboratory staff which was reported to have increased staff understanding of the various steps in the transfusion process. Laboratory staff are involved in collection and collation of audit data and it is planned to train key laboratory staff to conduct audit independently of the transfusion practitioners. The review team encouraged the board to ensure that laboratory staff in the SEBTC were also offered an opportunity to participate in audit within NHS Lothian. The review team commended the close working relationship between laboratories and the transfusion practitioners.

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 Lothian

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 Lothian blood transfusion policy states that all staff involved in the transfusion process must have received the appropriate training for their role. A comprehensive BBTP education programme is in place and the transfusion practitioners are responsible for identifying individuals who require blood transfusion training appropriate to their role. Transfusion practitioners are also notified of any relevant new employees. Staff reported that audit of the numbers of staff trained had been conducted and an audit of those staff who collect blood, started a few months prior to the review visit, had identified some categories of staff (eg ward clerkess) who had not yet been included in the rolling training programme. This is being addressed.

Attendance at training sessions is monitored and reminders to attend are sent via line management. For first year doctors, attendance can be traced using the Doctors Online Training System. However, access to information on the training status of individuals is not accessible for all staff groups and there is no formal mechanism whereby individuals who have not received training can be prevented from participation in the blood transfusion process. Staff reported that NHS Lothian is about to introduce BBTP Level 1: Safe Transfusion Practice training as a mandatory requirement for all staff involved in blood sampling, collection and administration and this had been included in relevant training agreements.

At the time of the review visit, a very high proportion of nursing staff, junior doctors, phlebotomists and clinical support workers had received BBTP Level 1 training. All new nursing and midwifery staff and operating department practitioners receive BBTP Level 1 training as part of their induction. Newly employed porters work alongside existing porters and are given protected time to attend a modified BBTP Level 1 training session. A proposal to include a check on attendance at BBTP Level 1 training in consultants' annual performance reviews was to be considered by the consultant/staff and associate specialist appraisal steering group committee in October 2007. The review team recognised the significant level of theoretical training achieved and encouraged the board to introduce a system for ensuring that only staff

who have completed the appropriate training should be involved in the transfusion process. Competency-based training and assessment is in place in accident and emergency areas and staff reported that a pilot scheme for competency-based training is being conducted in the intensive care unit at the RIE.

Participation in the SNBTS Trainers and Assessors Accreditation Programme is also under way.

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

STATUS: Not met

Audit of the completeness of the minimum data set on all transfusion documentation identified that this was not being recorded in all cases. This issue is being brought to the attention of the HTC.

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 Lothian

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 Lothian blood transfusion policy states that patients' observations are to be recorded (temperature, pulse and blood pressure) at the start of the transfusion and 15, 30 and 60 minutes after the start of the transfusion. Monitoring continues (minimum) hourly until the transfusion is completed. Observations in most areas are calculated using an early warning score chart (SEWS) which guides staff through the escalation procedures on how to manage and report any concerns about a patient's condition during transfusion. Staff training includes a section on the importance of observing any changes in the patient's condition following transfusion, however, an audit of the recording of the monitoring findings found that the observations are not always fully documented. This has been brought to the attention of the HTC for implementation of action to improve the recording of observations.

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

STATUS: Met

Any serious adverse events and near miss incidents relating to blood transfusion which occur in clinical areas of NHS Lothian are entered into DATIX by the relevant clinician. The transfusion practitioners also enter data on incident reports received from SEBTC quality assurance personnel. The practitioners investigate the incidents and report findings. Actions taken and recommendations for changes in practice are provided to the laboratory quality manager, the risk management facilitator at LUHD and to SEBTC QA staff.

A consultant haematologist would investigate any serious adverse event. Root cause analysis is conducted with any action required to prevent similar events, followed up by the quality improvement team. If a serious adverse event or near miss happens in the laboratory, SEBTC QA staff would contact the relevant clinical lead and suggest corrective action with a recommendation to contact the patient where appropriate.

The consultant haematologist would inform the patient of the details of the event and record this in the patient notes.

The transfusion practitioners and SEBTS QA staff feedback the outcome of incidents/near misses to clinical and blood bank staff through presentations, email alerts and incorporation into education for all staff groups.

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

A formal system is in place for reporting serious adverse events or reactions and near miss incidents to SABRE and the SHOT initiative. There are nominated individuals in each hospital within NHS Lothian who can prepare the reports. When the incident is reviewed by the transfusion team, it is agreed which individual is responsible to submit the report.

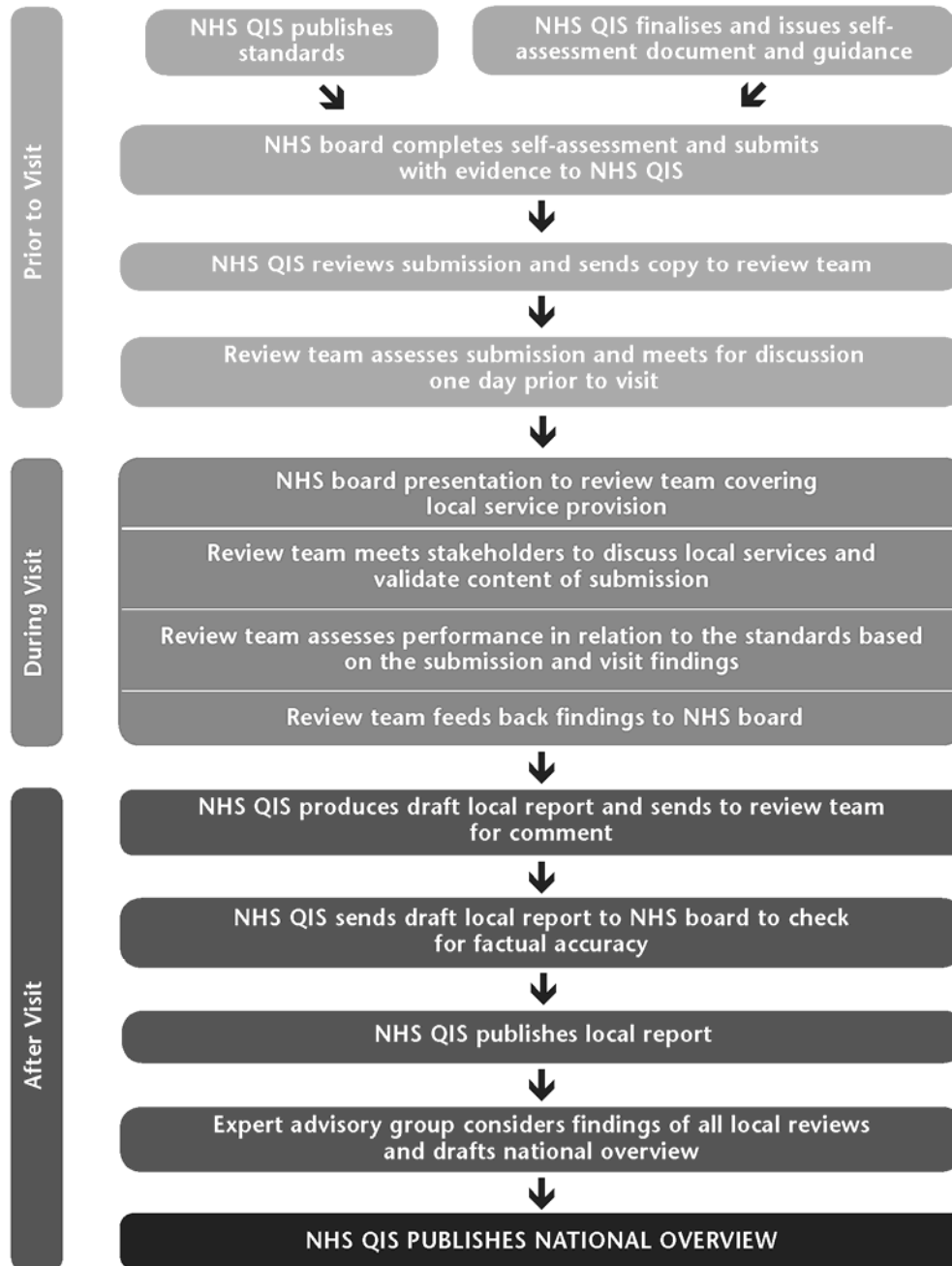
Serious near miss events and all SABRE and SHOT reportable incidents are reviewed by the NHS Lothian HTC.

Appendix 1 – Glossary of abbreviations

Abbreviation

BBTP	NHSScotland Better Blood Transfusion Programme
BCSH	British Committee for Standards in Haematology
CPA	Clinical Pathology Accreditation (UK) Ltd
EBMA	emergency blood management arrangements
HDL	Health Department Letter
HTC	hospital transfusion committee
LUHD	Lothian University Hospitals Division
MEL	Management Executive Letter
MHRA	Medicines and Healthcare products Regulatory Agency
MSBOS	maximum surgical blood ordering schedule
NHS QIS	NHS Quality Improvement Scotland
QA	quality assurance
RHSC	Royal Hospital for Sick Children
RIE	Royal Infirmary of Edinburgh
SABRE	Serious Adverse Blood Reactions and Events
SEBTS	Edinburgh & South East Scotland Blood Transfusion Service
SHOT	Serious Hazards of Transfusion
SNBTS	Scottish National Blood Transfusion Service
WGH	Western General Hospital

Appendix 2 – Review process



Appendix 3 – Details of review visit

The review visit to NHS Lothian was conducted on 6 September 2007.

Review team members

Dr Henry Watson (Team Leader)

Consultant Haematologist, NHS Grampian

Dr Chris Brammer

Consultant Haematologist, NHS Forth Valley

Mr William Davidson

Transfusion Laboratory Manager, NHS Lanarkshire

Mrs Ann Graham

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Project Manager, Scottish National Blood Transfusion Service

Ms Anne Simpson

Public Partner, Tayside

Ms Sheila Tunstall-James

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Ms Beverleigh Quested

Transfusion Nurse Educator, Australian Red Cross Blood Service (Observer)

NHS Quality Improvement Scotland Staff

Mrs Morag Kasmi

Senior Project Officer

Dr Avril MacLennan

Project Officer

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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