

NHS Western Isles

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 Western Isles'** 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 Western Isles** on **18 October 2007** can be found in Appendix 3.

2 Summary of findings

2.1 Overview of local service provision

The Western Isles is a name covering the Outer Hebrides, an island group situated north-west of mainland Scotland. The population of around 26,350¹ live on 10 islands, the largest and most populous of which is the Isle of Lewis where the town of Stornoway is located.

Local NHS system and services

Western Isles NHS Board has the same functions as mainland NHS boards. It is responsible for improving the health of the local population and for the delivery of the healthcare required. The NHS board provides strategic leadership and has overall responsibility for the efficient, effective and accountable performance of the NHS in the Western Isles.

At the time of the review visit, the NHS Western Isles hospital blood bank was based at the Western Isles Hospital, Stornoway, Isle of Lewis. The blood bank is supplied with blood and blood components by the North of Scotland SNBTS (Clinical Directorate) hospital transfusion laboratory (NBTS) which is based in Raigmore Hospital, Inverness. The Western Isles Hospital supplies blood and blood components for transfusion to Bethseda Hospice, Stornoway, Isle of Lewis; Uist & Barra Hospital, Balivanich, Isle of Benbecula, and to St Brendan's Hospital, Castlebray, Isle of Barra, which also holds a stock of blood for emergency use.

In a recent 12-month period, approximately 900 red cell units were transfused. Around 800 were used in the Western Isles Hospital, 40 in Uist & Barra Hospital, 40 in Bethseda Hospice and 10 in St Brendan's Hospital. Around 20 plasma units and five platelet units were used in the same period.

The NHSScotland Better Blood Transfusion Programme (BBTP) is supported by a transfusion practitioner based within Raigmore Hospital.

Further information about the local NHS system can be accessed via the website of NHS Western Isles (www.wihb.org.uk).

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

An NHS Western Isles multidisciplinary hospital transfusion committee (HTC) has been established, however, it has not been formally convened on a regular basis nor does it have clearly defined responsibilities and accountability to the chief executive via the clinical governance structure. The review team and the board recognised the challenge for the board to activate the HTC and to develop and maintain a multi-professional audit plan.

The HTC's involvement in promotion of the BBTP was reported to have been hindered by the lack of a dedicated training resource. The HTC was, however, encouraging all NHS Western Isles staff involved in the blood transfusion process to use the Better Blood Transfusion Continuing Education Programme elearning materials which can be accessed through the OrasGold™ online recording and assessment system. The review team recognised the challenge for the board in preparing a training and education programme for all staff involved in the blood transfusion process.

The HTC has drafted a blood transfusion policy and procedure manual, and several related clinical and laboratory protocols are also in draft form. Comprehensive emergency blood management arrangements (EBMA) are established, although the membership of the emergency blood management group (EBMG) has not been agreed. The review team encouraged the board to provide adequate resource to the HTC to assist with finalisation of these documents.

The laboratory manager is a member of the HTC and is the NHS Western Isles co-ordinator for collation of data on adverse events and near miss incidents relating to blood transfusion. Advice concerning incident reports can be sought from the laboratory manager in NBTS. Any training needs or changes in practice would be discussed with relevant staff, although there is no formal process for ensuring all relevant staff groups are made aware of any changes.

The review team commended the NHS Western Isles 'bag and tag' system to ensure that every unit of blood component received into the hospital laboratory can be unmistakably traced to its recipient, or its final fate if not transfused. NHS Western Isles laboratory staff audit traceability continuously and reported very high compliance with the system.

The protocol for the minimum identification data set used at every stage of the transfusion process does not include gender, although staff reported that gender was being included in practice. NHS Western Isles' policy is for all inpatients to wear an identification wristband, however, day patients who may require a blood transfusion do not wear an identification wristband. The review team encouraged the board to formalise its patient identification policy to include a process for alerting qualified practitioners to patients who have specific transfusion requirements, including the

wish to not be transfused. The policy should also include the current practice of recording of gender and a unique identifier for patients whose identity can not be confirmed.

Clinical management – pre-transfusion

Staff reported that the doctor prescribing a transfusion would discuss the potential risks and benefits of, and the alternatives to, transfusion with the patient and the patient would be offered an information leaflet. It was reported that this discussion would be recorded in the patient notes. Where pre-transfusion discussion is not possible, the reasons for the transfusion are discussed with the patient and written information offered retrospectively. For such patients there is also a system to investigate and act in accordance with the patient's treatment preferences including compliance with any advance decision document. All patients who have had a blood transfusion are advised of this in their discharge letter.

Blood samples for transfusion purposes are obtained and labelled in accordance with local protocols which are based on national guidelines. It was reported that all prescriptions for blood and blood components are adequately detailed and signed by a qualified practitioner.

Clinical management – hospital transfusion laboratory

The Western Isles Hospital laboratory was, at the time of the review visit, awaiting confirmation of continuing compliance with the Medicines and Healthcare products Regulatory Agency (MHRA) requirements. The review team commended the efforts made by the laboratory staff for their preparations for a mock MHRA inspection and the development of an action plan. A proposal for an application for accreditation by the Clinical Pathology Accreditation (UK) Ltd (CPA) was under consideration by the board and the review team recognised the challenge that achieving CPA accreditation would pose. Laboratory staff undertake training on an ad hoc basis, although training records have been developed for future recording of all training undertaken.

It was reported that written protocols for optimising blood use are being followed, although these have not been formally approved by the HTC. There is a robust stock management system in place in the Western Isles Hospital laboratory to eliminate excess inventory of blood and blood components and reduce waste. Stock management is supported by an appropriate information technology (IT) system. The establishment of a multidisciplinary audit programme across laboratory and clinical areas was noted by the review team as a challenge for the board.

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

It was reported that positive patient identification is performed against the blood component and any accompanying documentation and that the transfusion process would be stopped if any discrepancies were found. There were no audit data available to substantiate this at the time of the review visit, although the audit tools had been provided by the transfusion practitioner based at Raigmore Hospital. No formal system is in place to ensure that only staff who have completed the BBTP

Continuing Education Programme appropriate to their role can participate in the blood transfusion process. The review team encouraged the board to prioritise the installation of the appropriate software to ensure that all relevant staff could access OrasGold™. The team also encouraged the board to assist the HTC in ensuring that all staff grades, including medical staff, undertake BBTP training.

Patients are monitored for any adverse events or reactions during and after the transfusion process, and the review team highlighted the good practice of recording observations directly onto an NSBTS-designed transfusion monitoring chart. Any untoward events would be reported immediately to the Western Isles Hospital laboratory where the clinical incident reporting system ensures reports of serious adverse events or reactions and near miss incidents would be appropriately investigated and reported to the relevant national agencies.

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 Western Isles

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

An NHS Western Isles hospital transfusion committee (HTC) has been established and the review team considered its multidisciplinary membership to be comprehensive. A video link to Raigmore Hospital, Inverness, is used for communication with the clinical director, North of Scotland Blood Transfusion Centre (NSBTS) and the transfusion practitioner based at Raigmore Hospital, who are members of the HTC. The HTC has, however, not been formally convened on a regular basis due to a large number of meeting apologies and a lack of administrative support for the committee. Staff reported that dates for HTC meetings to be held in 2008 have been planned well in advance with the aim of improving attendance. At the time of the review visit, the HTC did not have a defined documented remit with clear responsibilities, although staff reported that the need to draft new terms of reference had been recognised, but had not been prioritised.

The HTC reports to the NHS Western Isles safe and effective care committee (SECC) through sending copies of meeting minutes for its consideration and agreement on matters for referral to the board's clinical governance committee (CGC). The review team did not see evidence of a clear reporting structure from the SECC to the board's CGC for blood transfusion related matters. The HTC also reports back to various clinical management teams (CMTs).

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

At the time of the review visit, the HTC was not involved in multi-professional audit. Staff reported that the board was aware of the need to implement an agreed audit

programme related to blood transfusion and was actively encouraging senior house officers to participate in audit. The lack of progress in this area was reported as due to the vacant post of clinical audit facilitator.

The review team was informed that, when able to convene, the HTC discussed continuing education and training for all staff involved in the blood transfusion process. It was further reported that there have been human resource difficulties associated with delivering face-to-face training sessions and the HTC has been encouraging the use of the NHS Scotland Better Blood Transfusion Continuing Education Programme elearning materials which can be accessed through the OrasGold™ online recording and assessment system. However, the software to run OrasGold™ is not installed on all relevant workstation computers or available for use on the computers within the library at the Western Isles Hospital. This has delayed the blood transfusion training and, at the time of the review visit, there was no timetable for installation of the relevant software across NHS Western Isles.

A blood transfusion policy and procedure manual has been drafted by the HTC, but requires further review. No timetable for the implementation of this manual has been set by the board. The risk management committee and relevant CMTs initially review all HTC approved guidelines and protocols. Further recommendations or amendments are then undertaken by the HTC before presenting to the SECC and the CGC for final approval and release. Staff reported that there was no clear system for ensuring that any newly approved document was circulated to all relevant areas and that this would be addressed.

The review team commended the protocol in place for blood transfusion care at home, although noted that it should be updated if it is to be implemented. Staff reported that the requirement for home transfusion had declined following the establishment of the Bethseda Hospice.

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

STATUS: Not met

The HTC does not have a collaborative working relationship with the CGC to implement the changes required by the NHSScotland Better Blood Transfusion Programme (BBTP) and to achieve the programme aims. The transfusion practitioner resource provided to NHS Western Isles is recognised by the HTC as inadequate. Also, the review team noted that the chair of the HTC and their acting deputy did not appear to be empowered by the board to ensure active local co-operation with full commitment from clinicians to achieving the programme aims.

The training element of the BBTP has been sporadic due to lack of resource and staff reported that the professional practice development manager has been assigned

to assist with this. The review team identified that additional resource from the blood transfusion link nurses in ward areas of the Western Isles Hospital is also available.

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 adverse events and near miss incidents are recorded on a procedure and incident log form which is submitted to the hospital transfusion laboratory in the Western Isles Hospital. Staff reported that the log forms are readily available in all areas where blood transfusion takes place. The laboratory manager reviews the log form and determines appropriate reporting action depending on the severity of the incident. If the incident is serious, an incident record form (IR1) is also completed and the NHS Western Isles incident management policy is followed.

The laboratory manager, a member of the HTC, convenes other members of the HTC if necessary to discuss potential action to be taken on a particular incident. Further advice can also be sought from the laboratory manager of the NSBTS when required. The clinical director of NSBTS, also a member of the HTC, shares lessons learned from adverse events and near miss incidents that occur in NHS Western Isles with the Scottish National Blood Transfusion Service (SNBTS) regional transfusion committee.

The review team was informed that if a local training issue is identified, the NHS Western Isles laboratory manager contacts the ward manager or consultant directly and prepares a training memorandum for general distribution. The review team noted the good lines of communication between the laboratory and ward areas.

Changes in practice, in response to blood transfusion related incidents would be reflected in the blood transfusion policy and procedure manual (currently in draft format), although staff reported that there is no defined process for ensuring that all relevant staff groups are made aware of the changes.

The review team acknowledged the verbal report of current practice for reporting and reviewing blood transfusion incidents and events, but considered the board not to have met this standard criterion as the HTC does not meet regularly. There was also insufficient evidence provided to conclude that the HTC was actively involved in reviewing incidents on a formal basis.

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 Western Isles

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 Western Isles Hospital laboratory 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 self-adhesive 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 return labels are entered into the computerised system that records the fate of each component. Paper copies of the returned labels are held securely in the laboratory until permanently archived and the computer files are backed up.

While the computer technology supporting this 'bag and tag' system has not been tested, the laboratory was able to respond to an enquiry from SNBTS to identify patients who had received specific units.

A daily check list of issued units is held in the laboratory and instances of non-returned labels can be quickly identified and corrective action taken. Non-return data are produced for each hospital and each ward area within the Western Isles Hospital. The review team encouraged the board to give consideration to sharing these data with staff in the hospitals and ward areas to encourage 100% compliance in all areas.

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 Western Isles

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 draft blood transfusion policy and procedure manual describes the system in place to ensure that the minimum identification data set is used at every stage of the clinical transfusion process to positively identify the patient. This data set is defined in the draft manual for each stage of the process, although it does not include gender at every stage. Staff reported that gender was being included in practice.

Addressograph labels with the complete data set for the patient are used on the transfusion forms, however, the prescription form does not have a specific space to prompt recording of date of birth and gender should a label not be available.

The BBTP Level 1: Safe Transfusion Practice training includes a section on the importance of correct patient identification and this formal programme, although started, has been delayed by the conflicting work commitments of the trainer. Staff reported that informal patient identification training is in place on the wards and that there had been no individual training issues identified. Ward managers ensure the ward staff have adequate training in positive patient identification.

While the board uses the four unique identifiers as described in the British Committee for Standards in Haematology (BCSH) Guidelines (2004) the omission of gender, at each stage of the clinical transfusion process means that the board has narrowly failed to meet this standard criterion.

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

Patients admitted to hospital within NHS Western Isles are issued with a wristband which includes the minimum identification data set. Staff reported that if the wristband became inaccessible or lost it would be replaced immediately and would be attached to a patient's ankle if their wrist was unsuitable. The theatre careplan in use in Western Isles Hospital includes a checkbox to confirm that the wristband is in

place. There is no other risk-assessed form of identification, although staff reported that this is being considered for inclusion in a patient identification policy which is being developed by the hospital services division of NHS Western Isles, alongside an action plan for standardising patient wristbands that meet the National Patient Safety Agency's (NPSA's) design requirements. Photographs of patients are used in certain ward areas to assist with identification, although the accompanying information does not conform with the minimum identification data set.

Day patients who may require a blood transfusion do not wear a wristband. Staff reported that they do not only rely on their previous knowledge of the patient, but also ask the patient to identify themselves by name and date of birth. The details provided are then checked against the patient's notes.

No audit data were available to demonstrate compliance with the NHS Western Isles' current policy for wristband use.

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

The laboratory can record specific transfusion requirements such as the need for irradiated products and this information would be printed onto transfusion-related documentation. There is no other formal system to alert practitioners to patients who wish to not be transfused. There is a policy for management and consenting Jehovah's Witnesses who may carry a health care advance directive/release from liability card which details their wishes about medical care, including the direction that no blood be administered under any circumstance. A consent form has been prepared for such patients and would be filed in the patient's notes.

A separate policy is followed for the management of obstetric women who decline blood and blood products and their consent to treatment would reflect this. The review team commended a new consent form for all patients within NHS Western Isles which specifically includes consent to blood transfusion, however, the form had not been ratified at the time of the review visit.

Staff were in support of the review team's recommendation to file specific consents at the front of the notes and to include an alert system for such notes in the revised blood transfusion policy and procedures manual.

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

Staff reported that if the identity of a patient can not be confirmed after verbal questioning then accompanying family or friends would be consulted and the patient's personal belongings would be searched for identifying information. If the identity could still not be confirmed, the patient's gender and status as 'identity unknown' are entered on to the Emergency Department Information System (EDIS) which generates a unique number. The patient's gender, approximate age and the unique number are then added to the patient's wristband.

If identifying information becomes available for an 'unknown patient', the patient is subsequently given a Community Health Index (CHI) number and the laboratory staff would be informed. If blood had been previously requested a further blood sample would be collected from the patient containing the additional identifying information. The review team noted this to be an example of good practice which should be included in the proposed blood transfusion policy and procedures manual.

In addition, NHS Western Isles provides a telephone simultaneous translation service to support front-line staff communicating with patients who have insufficient English to be able to assimilate technical information. Sign language and an advocacy service are also available for patients with communication difficulties.

The review team encouraged the board to consider formalising current procedures and incorporate them into the proposed patient identification policy.

Standard 1d: Core Principles

Standard Statement

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

NHS Western Isles

Essential Criterion

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

STATUS: Met

NHS Western Isles has a comprehensive emergency plan for the management of blood shortages which includes guidance for the use of platelets as well as for red cells. This plan is initiated by the board's medical director and includes a clear communication cascade. At the time of the review, the membership of the emergency blood management group (EBMG), which would have executive authority to actively manage the plan, had not been agreed. The review team commended the inclusion of advice on platelets, although urged the board to formalise the EBMG at the earliest opportunity.

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 Western Isles

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 (insufficient evidence)

Staff reported that the patient's clinical need for transfusion is assessed by the medical team, and the prescribing doctor then discusses the reasons for transfusion and the valid alternatives with the patient. This discussion includes the option to refuse. The indication for transfusion is recorded on the transfusion monitoring chart and staff reported that the prescribing doctor would record the discussion in the patient's notes.

A generic consent form has been drafted which specifically includes consent to blood transfusion, however, the form had not been ratified at the time of the review visit. A separate consent form is used for Jehovah's Witnesses which includes a statement for the prescribing doctor to sign to the effect that they have explained the treatment options available.

The evidence available to the review team was insufficient to allow an assessment of performance against this standard criterion to be made.

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-produced leaflets on blood transfusion are given to patients at the time of the pre-transfusion discussion and are freely available in information racks on the wards.

Health information, including that on blood transfusion, is also accessible to patients and staff at computer access points in NHS Western Isles hospitals and a wide variety of other public locations throughout the Western Isles. These information 'kiosks' are provided as part of the Western Isles Patient & Carers Information Project and present the information in English and various other languages. Telephone simultaneous translation and sign language services are also available.

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

NHS Western Isles has a policy and procedure for living wills (advance directives) which ensures that measures are taken to try and establish if an advance decision document exists. In an emergency situation, accident and emergency staff would search the patient and their personal effects and ask accompanying family or friends if they were aware of the existence of an advance directive. Where time permits, the patient's GP would be contacted to enquire whether an advance directive existed.

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

The review team encouraged the board to include the accident and emergency procedure in the proposed blood transfusion policy and procedures manual.

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 when pre-transfusion discussion has not taken place, retrospective discussion takes place and patients are offered an information leaflet. All patients who have had a blood transfusion are informed of this in their discharge letter.

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 Western Isles

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 (insufficient evidence)

Blood transfusion guidelines for pre-transfusion blood sampling are available on the ward. While the NHS Western Isles guidelines do not currently include gender as part of the identification data set, it was reported as being included on the wristband and appears on the blood request form and in the venepuncture policy. Prior to blood collection, patients are asked to confirm their name, address and date of birth and these details are cross referenced against related charts and forms. The guidelines prohibit pre-labelling of sample tubes.

The NHS Western Isles guidelines will be replaced by the blood transfusion policy and procedure manual when it is ratified.

For 'unknown' patients, a unique S-number barcode is issued. This number is additional to the EDIS number and is attached to the blood request form. The S-number is written on the patient wristband for subsequent checking against blood units.

The review team encouraged the board to audit this process in order to demonstrate compliance with this standard criterion. Staff reported that the audit tool developed in Raigmore Hospital would be used when the vacant clinical audit facilitator post was filled. This tool will need to be modified to include checks on blood collection and labelling of samples.

Standard 2c: Clinical Management – Pre-Transfusion

Standard Statement

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

NHS Western Isles

Essential Criteria

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

STATUS: Not met (insufficient evidence)

All blood and blood products are prescribed by a qualified medical practitioner. Staff confirmed that they would not go ahead with a transfusion unless a signed prescription form was present in the patient notes.

The review team encouraged the board to audit prescriptions against this standard criterion in order to demonstrate compliance. The board planned to use the audit tool developed in Raigmore Hospital. It was also reported that junior medical staff were being encouraged to undertake audit in order to meet their core competencies.

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 (insufficient evidence)

The intravenous fluid prescription sheet and fluid chart have space to specify the blood component to be administered, the number of units, the duration of transfusion and any special requirements or instructions. The review team sighted evidence of completion of these charts, although encouraged the board to audit this in order to demonstrate compliance with this standard criterion.

Transfusion of neonates was reported as extremely unlikely - such patients would be transferred to the Princess Royal Maternity Hospital (PRMH), Glasgow. However, if necessary the PRMH neonatal unit transfusion protocol would be followed which specifies the volume of blood to be transfused in millilitres. The review team recommended to the board that a document control system be implemented to ensure that the most recent copy of externally produced protocols was always available.

Standard 3a: Clinical Management – Hospital Transfusion Laboratory

Standard Statement

Laboratory operations comply with current regulatory requirements.

NHS Western Isles

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 laboratory manager has prepared, for the board's consideration, an outline business case for funding to achieve accreditation by Clinical Pathology Accreditation (UK) Ltd (CPA) within the next 12-18 months. Accreditation would require a quality management system to be in place and staff reported that work had been started on compilation of a quality manual. At the time of the review visit, there was a service level agreement with NSBTS which provides for technical and clinical support, however, it does not include an external adviser for professional staff development as required by the CPA standards. Staff reported that consultant support is actively being sought in order to comply with these standards. The review team recognised that achievement of CPA accreditation is a challenge for the board.

A hospital blood bank annual compliance report has been submitted to the Medicines and Healthcare products Regulatory Agency (MHRA) although the laboratory had not, at the time of the review visit, received notification of its compliance status with MHRA requirements. Compliance had been noted for the previous year. The review team commended the fact that the laboratory had participated in a mock MHRA inspection and received an action plan from the external auditor.

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

STATUS: Not met

Training materials for haematology are in use for biomedical scientific staff working in the Western Isles Hospital laboratory and training is conducted on a rota basis provided there is adequate availability of a senior biomedical scientist. Training records have been developed, however, at the time of the review visit, these had not been completed for all laboratory staff. The review team advised staff that, for

MHRA compliance, these training records should be modified to include reference to the relevant standard operating procedures.

Competency is assessed by observation and by participation in the NSBTS antibody screening proficiency test and the National External Quality Assurance Service (NEQAS).

Standard 3b: Clinical Management – Hospital Transfusion Laboratory

Standard Statement

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

NHS Western Isles

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

A maximum surgical blood ordering schedule (MSBOS) is in place, although the documentation is not dated nor endorsed by the HTC. The protocol for massive blood loss is in draft form having been agreed by the HTC and is awaiting review by the risk management committee and the SECC.

The laboratory has an action list in the event of a major incident and this is included in the NHS Western Isles major incident plan. A standard operating procedure is also in place for emergency blood ordering.

Emergency blood management arrangements (EBMA) involving membership from the HTC are in place, although the documented plan is awaiting ratification.

A monthly report on reasons for non-use of blood units is prepared for the HTC, however, the review team noted that the HTC did not meet regularly. The review team encouraged the board to provide resource which would ensure that the HTC is re-activated and that all the draft documents related to blood transfusion are finalised.

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

STATUS: Met

There is a standard operating procedure for stock maintenance of blood and blood products which includes processes for alerting laboratory staff to short-dated stock. Reports on red cell stocks are prepared daily for submission to NHSScotland's blood stock management scheme.

The Western Isles Hospital protocol for the use of blood in emergency situations was in draft form at the time of the review visit, although a standard operating procedure exists for emergency cross-matching of blood and issue of emergency O RhD negative stock for patients with immediate blood requirements.

An information technology (IT) system which includes a barcode reader supports the stock management and traceability system in the Western Isles Hospital laboratory.

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

STATUS: Not met

Staff reported that an audit action plan would be developed as part of the CPA accreditation process. Laboratory staff have conducted some audit related to reducing excessive inventory, but this did not include collaboration with clinical staff despite the good working relationship between the laboratory and clinical staff which the review team observed. Continuous traceability data are available, although are not reported back to clinical staff. The review team encouraged the laboratory staff to review blood wastage by ward or clinical specialty and report these findings and the traceability data to the clinical staff involved.

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 Western Isles

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

Face-to-face BBTP level 1 training sessions for all staff involved in the blood transfusion process have been held, but attendance has not always been prioritised, and, at the time of the review visit, it was estimated that about two thirds of nursing grade staff had been trained and some had been re-trained since the training started in 2003. The biomedical scientist that delivers the BBTP training has not had adequate time to maintain a training attendance database to identify staff not yet trained. Responsibility for staff training has been passed to the human resources department. Staff reported that the professional practice development manager has been assigned to assist with BBTP training and has included sessions in a corporate intranet learning events calendar.

The review team encouraged the board to prioritise the installation of the software to run OrasGold™ on all relevant workstation computers and in the library in the Western Isles Hospital. This would assist the NHS Western Isles literacy facilitator to continue to support the BBTP elearning modules. The review team also encouraged the board to consider giving protected time to the blood transfusion link nurses to deliver training in ward areas of the Western Isles Hospital.

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

STATUS: Not met

Addressograph labels with the complete data set for the patient would be used on the transfusion forms however, the prescription form does not have a specific space to prompt recording of date of birth and gender should a label not be available.

Checks are in place to ensure that the transfusion process is halted if any discrepancies in the minimum data set are found. Staff reported that audit of the completeness of transfusion documentation using the audit tool developed in Raigmore Hospital would be started when successful recruitment to the vacant clinical audit facilitator post was made.

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 Western Isles

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 (insufficient evidence)

Staff reported that patients are directly observed for the first 15 minutes of transfusion and closely observed for up to 30 minutes following the start of transfusion according to the blood transfusion policy and procedures manual (draft). Patient temperature, pulse and blood pressure are recorded just before transfusion starts and at 15 and 30 minutes following the start and then hourly until the transfusion is complete. The review team considered the use of the NSBTS-designed transfusion monitoring chart to be a good way of directly recording observations.

The patient is asked to use their call bell immediately if they become aware of symptoms during transfusion and staff reported that they would contact the Western Isles Hospital laboratory for advice if they suspected a transfusion reaction or incompatibility. A communication flow chart is available in ward areas which provides contact telephone numbers for clinical staff in Raigmore Hospital and staff in the laboratories at Western Isles Hospital and Raigmore Hospital both during normal office hours and out-of-hours.

As no audit data were available on patient observations, the review team could not determine whether this standard criterion was met.

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

STATUS: Met

Adverse events and near miss incidents related to blood transfusion are recorded on a procedure and incident log form which goes to the laboratory. A transfusion reaction report and SNBTS red cell transfusion reaction investigation form would also be completed where indicated. Algorithms are used to classify the seriousness of the incident and determine the appropriate follow-up action and advice is sought from a medical officer in NSBTS.

The background to incidents is investigated and issues identified are discussed between the laboratory and clinical staff directly. Any lessons learned from incidents would be shared at the monthly ward meetings or via the ward communication book for staff who can not attend the meetings.

A policy for the management of transfusion reactions has been drafted with a copy in the laboratory and the review team encouraged the board to provide adequate resource to ensure this policy could be finalised.

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

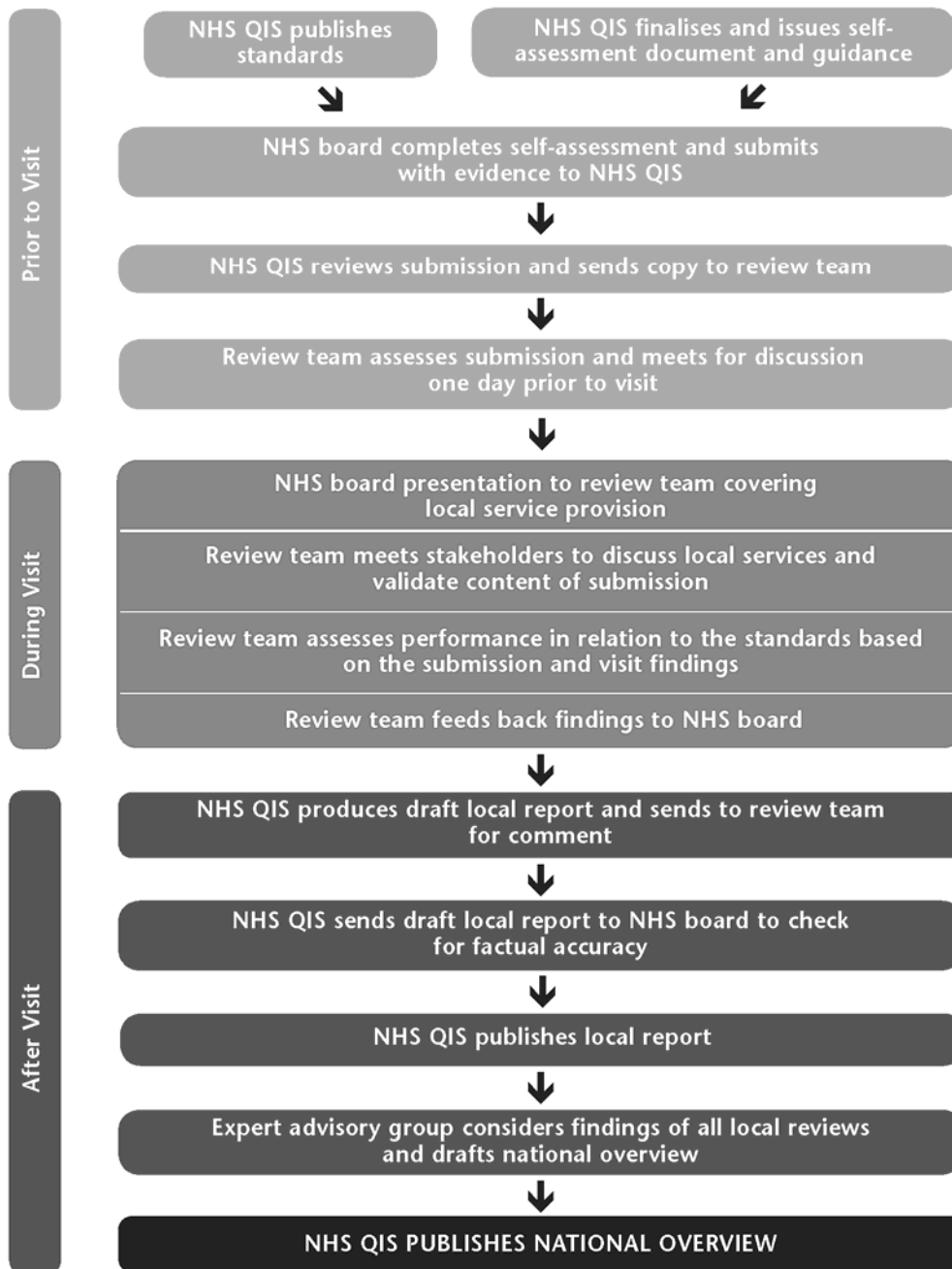
The blood transfusion policy and procedure manual (currently in draft) and a laboratory standard operating procedure describe the process for reporting to Serious Adverse Blood Reactions and Events (SABRE) and the Serious Hazards of Transfusion (SHOT) initiative. At the time of the review visit, there were two named biomedical scientists who could access the electronic reporting system. The review team encouraged the laboratory manager to provide another biomedical scientist with training and access to the reporting system.

Appendix 1 – Glossary of abbreviations

Abbreviation

BBTP	NHSScotland Better Blood Transfusion Programme
BCSH	British Committee for Standards in Haematology
CGC	clinical governance committee
CHI	Community Health Index
CMT	clinical management team
CPA	Clinical Pathology Accreditation (UK) Ltd
EBMA	emergency blood management arrangements
EBMG	emergency blood management group
EDIS	Emergency Department Information System
GP	general practitioner
HTC	hospital transfusion committee
IT	information technology
MHRA	Medicines and Healthcare products Regulatory Agency
MSBOS	maximum surgical blood ordering schedule
NBTS	North of Scotland Blood Transfusion Service
NEQAS	National External Quality Assessment Service
NHS QIS	NHS Quality Improvement Scotland
NPSA	National Patient Safety Agency
PRMH	Princess Royal Maternity Hospital
SABRE	Serious Adverse Blood Reactions and Events
SECC	safe and effective care committee
SHOT	Serious Hazards of Transfusion
SNBTS	Scottish National Blood Transfusion Service

Appendix 2 – Review process



Appendix 3 – Details of review visit

The review visit to NHS Western Isles was conducted on 18 October 2007.

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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 NHS Scotland, 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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