

**Title:**

SNBTS POLICY ON THE ACCEPTANCE CRITERIA FOR PATIENT BLOOD SAMPLES WITHIN PATIENT SERVICES LABORATORIES

Background:

Errors which occur during the pre-transfusion blood sampling process are a potential source of patient harm. Undetected patient mis-identification may result in the transfusion of ABO incompatible blood or blood components with potentially fatal consequences. A robust laboratory sample acceptance policy is recommended by BSH Guidance and UKAS to help reduce the risk of such events, by identifying samples which have been labelled incorrectly and rejecting them before any testing is performed.

This document outlines the SNBTS approach to sample acceptance. A risk based review of the previous version of this policy was performed, with a particular focus on samples for tests other than pre-transfusion testing, where the consequences of patient misidentification are less grave. This most recent version incorporates new guidance for the acceptance criteria to be applied to non-pre transfusion samples processed in Patient Services laboratories including hospital blood banks, red cell immunohematology laboratories and histocompatibility and immunogenetics laboratories.

Note: This policy does not apply to samples relating to donors of blood, tissue or cells

Key Changes from Previous Revision	
CR 16963 incorporated at section 1.8 to include that the EFI standards references are the 8 th version.	

Policy Agreement	CGSG: N/A	SMT: N/A
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1 Background

1.1 Errors occurring during the pre-transfusion sampling process are a potential source of patient harm. This is illustrated by SHOT data with the most recent SHOT report¹ identifying 792 'wrong blood in tube' (WBIT) events, making it the single most common type of 'near miss' event reported. In just over half of cases, an ABO incompatible transfusion may have been administered had the error not been detected. The incidence of WBIT events vary between studies but are of the order of 1 in 1000 samples drawn².

1.2 It is well recognised that inappropriately or mislabelled samples are more likely to contain blood from the wrong patient, supporting the use of sample acceptance policies which reject mislabelled samples. The incidence of WBIT has been demonstrated to be up to 55 times higher in mislabelled samples than in those correctly labelled at the time of sampling^{3,4}. Other studies have shown that strictly enforced sample acceptance policy can significantly reduce the incidence of WBIT events and mislabelled samples⁵.

1.3 The British Society for Haematology (BSH) Guidelines on the administration of blood components 2009⁶ recommended a zero tolerance approach be applied to pre-transfusion samples:

"12.3 Organisations should have a clear policy on the rejection of pre-transfusion blood samples which do not meet minimum labelling requirements. There should be no changes or amendment of patient core identifiers once samples have been sent to the laboratory. It is suggested that organisations should adopt a 'zero tolerance' policy."

The need for a clear pre-transfusion sample acceptance policy is reiterated in the updated BSH guidance published in 2017⁷ and also in the BSH Guidelines for pre-transfusion compatibility procedures in transfusion laboratories⁸.

1.4 The BSI Standards for Medical Laboratories: requirements for quality and competence (ISO15189:2012) set out standards for the content of request forms and instructions for collection activities. These include sample labelling that '*provides an unequivocal link with the patients from whom they are collected*'. The standards also require '*laboratory-developed and documented criteria for sample acceptance or rejection of samples*'.

1.6 The risk conveyed by mis-identification of blood samples varies with the tests to be performed. As discussed above, the risk of mis-identification of a pre-transfusion sample is that the patient may receive an ABO incompatible blood or blood component transfusion which may have fatal consequences. Conversely, the risk associated with samples not for pre-transfusion testing may be lower, and risk assessment of the different sample types can be applied to attempt to quantify this risk.

1.7 The previous version of this policy, NATP CLIN 037 03, advocated a zero tolerance approach for all samples sent for testing in SNBTS patient services laboratories. As such, it stated that samples which did not meet the policy standard should be rejected and applied to all sample types. This blanket approach was chosen to standardise processes and aimed to ensure that samples which were accepted by one laboratory were accepted by all: particularly important for samples being referred from one site to another for testing. The policy also stipulated that if a sample which failed to meet these acceptance criteria was accepted for testing, an incident must



be raised through the SNBTS incident management system. On review of these reported incidents, it became clear that certain sample types were accepted when labelling did not meet the policy standard and that the clinical reasoning applied to these decisions indicated a review of this blanket 'zero tolerance' approach was justified.

1.8 The 8th Version of the European Federation for Immunogenetics (EFI) Standards for Histocompatibility and Immunogenetics testing became effective in January 2020⁹. These standards stipulate that samples must be individually labelled with the name, and/or other unique identification marker of the individual (C3.1.4.1). It is therefore reasonable that some SNBTS H&I samples are subject to these same acceptance criteria rather than the more stringent criteria applied to samples submitted for pre-transfusion testing.

1.9 Samples are also processed within SNBTS patient services transfusion laboratories which are **not** for pre-transfusion testing. These include assessment of fetomaternal haemorrhage (FMH) by acid elution (Kleihauer) and flow cytometry, quantification of maternal anti-D and anti-c antibodies detected in pregnancy and DAT tests for AIHA and transfusion reactions. While misidentification of such samples is clearly not desirable, it does not carry the same potentially fatal sequelae of a misidentified pre-transfusion sample. It is therefore reasonable that these samples be subject to different sample acceptance criteria.

Statement Of Policy

2 Pre Transfusion Samples- Zero tolerance approach

Pre-transfusion samples which do not meet the following criteria will be rejected and a new sample will be required.

2.1 Pre-transfusion sample tubes and request forms must be labelled with the following **four** points of patient identifying data (core identifiers) as detailed in the BSH guidelines:

- Last Name (spelt correctly)*
- First Name (spelt correctly) *
- Date of Birth
- Unique Identification Number (CHI or Hospital Number where no CHI number is available)

*For patients who change forename, surname or both please refer to national SOP NATS CLS 041.

2.2 Unknown patients

2.2.1 Where patients are unidentified at the time of sampling, it is best practice to use an additional non-sequential numerical identifier (eg Typenex)

2.2.2 The minimum acceptance criteria for pre-transfusion samples from unidentified patients are:

- Typenex number/ A&E Number/ Organ Donor Transplantation Number/ other unique identifier
- Gender



2.3 Electronic requests

2.3.1 Sample tubes must be hand written unless secure bedside electronic labelling systems are in place. These are not in place in Scottish hospitals at present.

2.4 There **must** be no discrepancy between the patient identifying information on the sample tube and request form. If names are in a different order on sample or form, and the CHI number is identical, after contacting the clinical area to confirm the correct order, the sample can be accepted.

2.5 It **must** be clear to Laboratory staff that there has been no attempt made to replace a *different* patient's details on the sample tube, therefore any sample tube where any patient core identifier has been obliterated either by correction fluid or by pen will be discarded. Minor amendments or corrections, where it clear both refer to the same patient can be accepted.

2.6 Pre transfusion samples and/or request forms for pre-transfusion testing are also expected to have:

- the gender of the patient
- the date and time on which the sample was taken
- the signature or initials of the person taking the sample

Where this information is not given, a sample may be tested, after contacting the ward to clarify the patient's gender and the date and time the sample was taken.

Unsigned samples may be tested so long as the requesting doctor and phlebotomist have signed the request form.

2.7 Pre-transfusion request forms should also give *legibly*:

- the name of the person authorising the test / transfusion
- the location of the patient
- relevant clinical details regarding the diagnosis, the reason for transfusion and the rationale for any special requirements for components ordered

Although this information is desirable, its absence will not impact patient testing.

2.8 Under no circumstances can the sample or request form be altered by the clinical area after receipt.

2.9 In exceptional circumstances a BTS Consultant, Specialty Doctor or Consultant Clinical Scientist or the Laboratory Manager may agree to process a sample that fails to meet the standards set out above. All such incidents must be reported through the SNBTS Incident Reporting System.

2.10 In urgent cases when a sample does not meet these requirements, emergency blood should be issued in order to avoid unnecessary delays whilst a correctly labelled sample is awaited.



3. Other blood sample types

3.1 Red Cell Immunohaematology (RCI) samples

3.1.1

Sample type
FMH estimation by flow cytometry

Non pre-transfusion samples listed above can be accepted where they meet the following criteria:

- Samples are labelled with the four core patient identifiers in Section 2.1
- Addressograph labels are acceptable (forms and sample tubes)

3.1.1.2

Samples for FMH estimation sent from Western Isles Hospital are exempt from the above and must be hand labelled. FMH estimation for these samples is performed initially by flow cytometry. In some cases, estimation by flow cytometry will not be possible (for example neonatal weak D) the sample will be referred for FMH estimation by Kleihauer test. The sample must therefore meet the standard sample acceptance criteria (see section 2).

3.1.2

Sample type
Aliquot of sample for anti-D or anti-c quantitation received from SNBTS laboratory

Non pre-transfusion samples listed above can be accepted where they meet the following criteria:

- Samples are labelled with the four core patient identifiers in Section 2.1

3.1.3

Sample type
Blood samples from allogeneic stem cell donors

Non pre-transfusion samples listed above can be accepted where they meet the following criteria:

- Samples are labelled with a unique identifier

3.2 Histocompatibility and Immunogenetics (H&I) samples

H&I sample type
HLA type and HLA antibody screen
Flow crossmatching for transplant patients

The H&I sample request form explains the need for samples to be labelled as in 2.1. However, non pre-transfusion samples listed above can be accepted where they meet the following criteria:

- CHI is present on form only
- CHI is present on sample only



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- Tissue samples labelled with only the ODT unique identifier, as long as additional donor information is available on the form
- Also note that Addressograph labels are acceptable (forms and sample tubes)

3. References

1. S Narayan (Ed) D Poles et al. on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. The 2018 Annual SHOT Report (2019)
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3. Lumadue JA, Boyd JS, Ness PM. Adherence to a strict specimen labelling policy decreases the incidence of erroneous blood grouping of blood bank specimens. *Transfusion* 1997; 37: 1169-1172
4. Strauss R, Downie H, Wilson A, et al. Sample collection and sample handling errors submitted to the transfusion error surveillance system, 2006 to 2015. *Transfusion*. 2018;58(7):1697-1707
5. O'Neill E, Richardson- Weber L, McCormack G et al. *Am J Clin Pathol* 2009; 132: 164-68
6. Harris AM, Atterbury CLJ, Chaffe B et al. BSH Guidelines on the administration of blood components BCSH 2009
7. Robinson S, Harris A, Atkinson S et al. The administration of blood components: A British Society for Haematology Guideline. *Transfusion Medicine* 2018; 28: 3-21
8. Milkins C, Berryman J, Cantwell C et al. Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories *Transfusion Medicine* 2013; 23: 3-35
9. <https://efi-web.org/committees/standards-committee>