Standards for the Acceptance of Pre-transfusion Samples in Wales

Background

The safety of blood transfusion depends on correct patient identification at all stages of the process, starting crucially with accurately labelling the pre-transfusion sample with details of the patient from whom it is taken.

Errors occur at this stage of the process when a blood sample is incorrectly collected (from the wrong patient) or mislabelled (with one of the four core identifiers missing, incorrectly written or illegible), with the potential for the wrong blood being given to the wrong patient.

The British Society for Haematology (BSH)[1] state that '*the collection of the blood sample from the patient and the subsequent completion of details on the blood sample tube must be performed as one continuous, uninterrupted event at the patient's (bed)side involving one patient and one trained, competent and locally designated member of staff'.*

As a minimum, the details on the pre-transfusion sample should include the following:

- Core patient identifiers: first name, last name, date of birth, unique identification number
- Date and time sample taken
- The identity of the member of staff taking the sample.

N.B. The first line of address may also be required in some Health Boards. This will be defined in local policy.

The sample must be labelled **after** being taken **whilst still at the patient's side**, the details must be handwritten or using a label generated at the patient's side by an 'on-demand' label printer validated for this purpose.

It is a Medicines and Healthcare products Regulatory Agency (MHRA) requirement that laboratories should have policies in place for managing incorrectly labelled specimens, and that these policies are strictly adhered to.

UKAS (United Kingdom Accreditation Service) ISO 15189[1] defines the requirement for the date and time a sample was taken as part of their medical laboratory standards.

Robust sample rejection policies normally referred to as a Zero Tolerance approach, reduces the risk of assigning the wrong result to a patient but can potentially lead to delay in availability of results and in delivery of compatible blood. Consistent application of national recommendations for sample labelling and acceptance across both hospital and reference laboratories is a major contribution to improving patient safety.

The standards for pre-transfusion sample acceptance in Wales were introduced in 2010, with the Blood Health National Oversight Group (BHNOG) now being responsible for approving review and changes.

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Literature and Evidence Considered

BSH Guideline for the haematological management of major haemorrhage (2022)[2]
The most significant adverse transfusion-associated event in emergencies is ABO mismatched transfusion. Robust patient and sample identification systems for unknown patients are essential to avoid errors in emergency and multiple casualty situations. All patients receiving a blood transfusion must wear a patient identification wristband containing the unique identifier.

PSN 066 Safer Temporary Identification Criteria for Unknown or Unidentified Patients (2023)[3]: *All organisations with Emergency Departments should develop a system for unique temporary identification of unknown patients using the system outlined in this PSN.*

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Introduction

The collection of patient blood samples for pre-transfusion testing is a vital step in the blood transfusion process. It is essential that completion of the transfusion request form, taking of samples, labelling of samples and declaration of a full patient identification check is performed correctly to both ensure patient safety and maintain the quality of the transfusion process.

The following ***quality requirements*** and criteria highlight essential aspects of the sampling process and are mandatory. Application of these standards supports a unified approach to **zero tolerance** across Wales.

Purpose of the Information

The information on the form allows confirmation of the core identifiers with the patient prior to sample-taking.
The information on the sample allows confirmation of its correct origin prior to laboratory testing.

Function of the Form

The specific purpose of the form is:

- To provide an instruction to take a blood sample from the patient.
- To be used as part of the patient identification process where the core identifiers are verified verbally by the patient (whenever possible) and checked against the identification wristband.
- To communicate the request to the transfusion laboratory, i.e. what is required, for which patient and where and when it is needed.
- To provide confirmation to the laboratory that the sample taker verified the patient's identity before taking the sample.

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Key Elements

1. Patient Identification

Four points of patient identification are required:

NHS or hospital number Last name First name Date of birth	*Must match exactly with the corresponding information on the request form. Discrepancy in any of these fields constitutes a failed sample in accordance with zero tolerance.*

2. Signatures

- The name, signature and professional registration number should be documented on the transfusion request form by the person making the request; this provides sanctioned instruction for the blood sample to be taken.
- The name and signature should be documented on the form by the person taking the sample; this is the declaration that the patient was identified before the sample was taken and that all details matched verbally (whenever possible), identification wristband and transfusion request form.
- The signature on the sample confirms that the person signing acknowledges **their** responsibility for the sample being correct.

3. Date and time of sample

The date and time on the sample is a UKAS[1] requirement; these data ensure that the sample is within a suitable timeframe for testing and provide a reference for assessing the validity of the sample for issuing blood components.

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Identifiable Patients

Quality Requirement 1

The **sample** must contain all the following and must match exactly with the corresponding information on the transfusion request form:

Core Identifiers:

1. NHS number or hospital number
2. Last name
3. First Name
4. Date of birth
5. Collector's signature

If any of the criteria are missing or discrepant the sample must be retaken

Additional information (not relevant for the purposes of confirming correct sample ID):

6. Date collected must also be present on the sample (UKAS requirement)
7. Time collected must also be present on the sample (UKAS requirement)

Quality Requirement 2

The sample tube must be either:

a. Handwritten and legible
   or
b. Completed with a label produced at the bedside and electronically generated by scanning the patient's identity wristband.

If core identifiers 1 – 4 on the form and sample do not match, the sample must be discarded, and the relevant person informed that a new sample is required. In an emergency where blood is required urgently the clinician should be informed to use Group **O** blood (in accordance with BSH guidelines[2]) until a correctly labelled sample is received.

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Unknown patients without capacity or unable to provide verbal identification.

This group of patients are particularly vulnerable, especially in acute or emergency situations. It is essential that these patients are individually and uniquely identified.
Where patients are unknown and unable to provide verbal identifiers, the same principles apply as for patients who can identify themselves. The purpose is therefore to use the same number of identifiers. The requirements used for such patients are defined in PSN066: *Safer Temporary Identification Criteria for Unknown or Unidentified Patients*[3].

Quality Requirement 1
The **sample** for an unknown patient must contain five points of identification, all of which must match exactly with the corresponding information on the request form. It is acknowledged that hospitals may already have systems in place, and these should be risk-assessed against the minimum standards for points of identification.

Minimum Criteria:

Known Patient Identifiers		Unknown Patient Identifiers
NHS number or hospital number	**1**	Unique identifier from local numbering system or emergency NHS number non sequential series of digits should be used
Last name	**2**	Randomly generated last name from an edited phonetic alphabet
First Name	**3**	Randomly generated first name from an edited phonetic alphabet
Date of birth	**4**	Estimated date of birth: Combine 01Jan with an estimated year of birth e.g. 01Jan1950. For neonates below the age of 1 year an estimation of months is required
——	**5**	Time of admission
Collector's signature	**6**	Collector's signature

If any of the minimum criteria are missing or discrepant the sample must be retaken

Additional information (not relevant for the purposes of confirming correct sample ID):

7. Date collected must also be present on the sample (UKAS requirement)
8. Time collected must also be present on the sample (UKAS requirement)

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Quality Requirement 2

The sample tube must be either:

a. Handwritten and legible
   or
b. Completed with a label produced at the bedside and electronically generated by scanning the patient's identity wristband.

If all minimum criteria do not exactly match on the form and sample, the sample must be discarded, and the relevant person informed that a new sample is required. In an emergency where blood is required urgently the clinician should be informed to use **O** blood (in accordance with BSH guidelines[2]) until the correct sample is received.

References

1. UKAS: Medical Laboratories-Requirements for quality and competence (ISO 15189:2012): https://www.ukas.com/accreditation/standards/laboratory-accreditation/?gclid=Cj0KCQjwoeemBhCfARIsADR2QCtUSE3wdsnVsPFRwosvb-rqlEDLkbfDgrH_4dt0Yx5MFi8GRSgsxy8aAsY4EALw_wcB
2. BSH: A practical guideline for the haematological management of major haemorrhage (2022) https://onlinelibrary.wiley.com/doi/10.1111/bjh.18275
3. PSN 066: Safer Temporary Identification Criteria for Unknown or Unidentified Patients (2023): https://bhnog.wales.nhs.uk/wp-content/uploads/2023/03/20230208-PSN066-Unknown-patients.pdf