SaBTO Patient Consent for Blood Transfusion

DRAFT Recommendations 2020

Summary

Informed consent should be obtained for those being given blood or blood components. These recommendations for consent cover transfusion of whole blood, red blood cells, platelets, fresh-frozen plasma (FFP), cryoprecipitate and granulocytes and exposure to blood or its components (such as in extracorporeal machine oxygenation). These recommendations apply both to autologous and allogeneic transfusions. Consent for receipt of blood *products* (such as albumin or intravenous immunoglobulin) are out of scope as these products are classified as medicinal products and subject to different regulations.

Consent should be proportionate, and we recommend that patients should be classified in one of 6 groups:

- The patient who is unlikely to receive a transfusion as part of a procedure during which time they will be incapacitated. They should be informed that transfusion is unlikely unless an unexpected emergency arises. The health care practitioner should ascertain whether the patient would consent to receive a transfusion under such circumstances and provide additional information about the transfusion only as required/requested by the patient.
- The patient will possibly/is likely to receive a transfusion as part of a procedure during which the patient will be incapacitated. This may be defined as requesting a 'group and save' sample. The health care professional should inform the patient that transfusion is possible/likely and provide a general explanation of the procedure, along with an explanation of the risks inherent in the procedure and the risks inherent in refusing the procedure and complete the informed consent for transfusion process and document this.
- The patient will definitely receive a transfusion. The health care professional should complete the informed consent for transfusion process and document this.
- The patient needs to receive a transfusion in an emergency situation and is unable to provide consent. The patient should be informed about the transfusion and its possible consequences as soon as appropriate.
- The patient is expected to receive multiple transfusions on more than one occasion. These patients will need ongoing information about risks, benefits and any potential alternatives. Long-term issues related to transfusion may include alloimmunisation and iron overload.
- The patient who refuses blood transfusion. Their wishes should be respected with relevant guidelines followed.

If the patient does receive a transfusion, the patient will need to be informed post procedure prior to discharge and retrospective patient information will be required.

We recommend that the UK Blood Services should provide a standardised source of information for both patients/public and also for healthcare professionals. Training in consent for transfusion should continue to be included in all relevant undergraduate healthcare professionals training, followed by continuous, regular knowledge updates (minimum 3-yearly) for all healthcare professionals involved in the consent for transfusion process. Compliance with these guidelines should be regularly audited by the regulatory authorities.

Introduction and Background

The need to review the 2011 SaBTO report titled *Patient Consent for Blood Transfusion* [1] was identified by the Chair of SaBTO. It was considered timely to do this as the report had been published more than eight years previously. Furthermore, since the initial report, the UK Supreme Court ruling in 2015 on informed consent clarified the guidance on consent in Lanarkshire and Montgomery [2] and the ongoing Infected Blood Inquiry identified concerns about whether and to what extent people were treated without knowledge or consent [3].

In November 2019 a SaBTO Consent working group was established and the membership is shown in appendix 1. The remit and scope of this group, approved by SaBTO, included the following:

- Review relevant updates relating to blood transfusion consent including the 2015 Montgomery [2] ruling. GMC Guidance [4] and updated UK vCJD precautionary measures [5]; 2015 NICE guidelines [6]; 2016 NICE Quality Standards [7]; and 2015 Choosing Wisely recommendations for blood transfusion [8].
- 'Blood transfusion' for the purposes of this working group refers to the transfusion of blood *components*, as defined by the Blood Safety and Quality Regulations (BSQR SI 2005 No.50 as amended)[9] who define blood components as a therapeutic constituent of blood [red blood cells, platelets, fresh-frozen plasma (FFP), cryoprecipitate and granulocytes]; it also includes whole blood. Blood *products* (such as albumin or intravenous immunoglobulin) are out of scope as these are classified as medicinal products and subject to different regulations.
- Inclusion of all patients who may be exposed to blood components (for example, including patients undergoing extracorporeal membrane oxygenation (ECMO), pump priming or organ perfusion).
- The recommendations are pertinent to both autologous and allogeneic transfusions as many of the most frequent serious risks of transfusion are similar (e.g. transfusion associated circulatory overload (TACO) and wrong blood component transfused.
- Recommendations must be in line with current legislation on consent and relevant regulations and must consider the operational impact of any recommendations.
- Consider the impact of recommendations on all stakeholders, including but not exclusively donors, patients and patient groups, the UK blood, tissues, cells and organ establishments, health care professionals involved in transfusion, the wider NHS, and the public.

The group met on 4 occasions and corresponded by email. Legal advice was sought from the legal representatives of all 4 UK nations. Before approval by SaBTO (Date), there were widespread consultations with interested parties (see appendix 2).

Since 2011, improvements in obtaining consent for transfusion has been made, but further progress is needed. In 2014, the National Comparative Audit of Consent for Blood

Transfusion [10] found that the implementation of informed consent for transfusion was sporadic and compliance with the 2011 SaBTO recommendations was generally low. Results included:

- 81% had documentation of the clinical indication for transfusion in the notes.
- 85% of staff stated that they had explained the reason for transfusion to the patient, but only 65% stated that they had documented this.
- Documentation of consent was only evident in 43% of notes reviewed, and patient recall was variable.

Anecdotal evidence and the experiences of the SaBTO consent working group members suggest that current practice remains similar.

The purpose of these new updated recommendations is to clarify existing practice and enhance standards for the provision of information about blood transfusion and obtaining patient consent.

The working group has taken into account the 2015 decision of the UK Supreme Court in Montgomery *v* Lanarkshire (UKSC 2013/0136) [2]. This was a landmark legal decision for informed consent and the shared decision-making model practiced in the UK. The court's decision redefined the standard for informed consent and disclosure. The Supreme Court held that a patient should be told whatever they want to know, not what the doctor thinks they should be told, and establishing a duty of care to warn of material risks. The test of materiality defined in the Montgomery ruling was whether "a reasonable person in the patient's circumstances would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it". The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. This clarifies that when seeking consent to treatment, the question of whether the information given to the patient is adequate is judged from the perspective of a reasonable person in the patient's position. For the purposes of consent, the ruling from Montgomery replaces the application of previous tests founded in Bolam and refined in Sidaway to consent establishing a duty of care to warn of material risks and the patient's right to make informed treatment decisions takes precedence above the doctor's professional judgment/discretion in disclosing information. Although Montgomery changed the legal position, the principle of involving patients in their treatment and sharing information with them about risks and benefits has been in place for some time. The Montgomery decision therefore clarifies the law of informed consent and aligns it with current GMC guidance. It represents a shift towards a more cooperative approach to consent between patients and medical practitioners. This means finding the time to explain the risks and benefits of a recommended course of action and the other options.

The ruling makes it clear that any intervention must be based on a shared decision-making process, to help patients make an informed choice.

The working group has also considered the National Institute for Health and Care Excellence (NICE 2015) Blood Transfusion guideline (NG24) [6] and the NICE (2016) Blood Transfusion Quality Standards [7], which includes the provision of verbal and written information.

Standards for Consent are available from the General Medical Council (GMC) [4] and these should be referred to for all aspects of consent including capacity to consent, patients who refuse treatment and consent in children.

Informed and Valid Consent:

All staff authorising blood components for patients should be familiar with the key principles of good practice in obtaining consent and aware of the range of ethical issues that commonly arise in transfusion practice. For the purpose of this paper, informed and valid consent is the process by which a patient learns about and understands the purpose, benefits, and potential risks of the transfusion. For consent to be valid, it must be voluntary, informed and given by a competent patient with capacity [4, 11,12]. Consideration should be given whether the transfusion is the only available treatment, whether any alternative treatments are available and suitable, and the risks and benefits of those alternatives as opposed to the transfusion. In addition to the provision of information about the nature and purpose of the proposed treatment, an active discussion should result in shared decision-making, allowing the patient to ask their own questions, and to raise any concerns they wish addressed, before they make a decision to receive, or refuse, the transfusion. The dialogue needs to be focused on the individual to ascertain what risks are or are not acceptable to that individual's circumstances. Non-medical considerations may influence a patient's choice. What is not a material risk for one patient may be a material risk to another. A doctor must provide information in a comprehensible way and ensure it is properly understood. The detail desired varies from patient to patient. The doctor's duty is not discharged by deluging a patient with technical information or by simply obtaining a signature on a consent form.

The amount of information required to make consent informed may vary depending on complexity and risks of treatment as well as the patient's wishes.

It is recommended that the following framework (adapted from the NICE Blood Transfusion Guideline 2015 NG24) [6] is used when providing verbal and written information to patients, and their family members or carers (as appropriate):

- the reason for the transfusion,
- the benefits of the transfusion,
- the risks of transfusion – both short- and long-term risks (and including any additional risks pertinent to long term multi-transfused patients),
- any transfusion needs specific to them.
- any alternatives that are available, and how they might reduce their need for a transfusion
- the possible consequences of refusing a blood transfusion

- the transfusion process
- that they are no longer eligible to donate blood
- that they are encouraged to ask questions.

If the patient changes their mind at any point before the transfusion, they are entitled to withdraw their consent.

Consent of children and young people should comply with GMC guidance [4].

Proportionality

There are a few exceptions when treatment may be able to go ahead without the person's consent, even if they are capable of giving their permission [13].NHS Guidance [13] states that 'it may not be necessary to obtain consent if a person needs emergency treatment to save their life, but they're incapacitated (for example, they're unconscious) – the reasons why treatment was necessary should be fully explained once they have recovered or immediately needs an additional emergency procedure during an operation – there has to be a clear medical reason why it would be unsafe to wait to obtain consent'. Shared decision-making does not apply where patients lack capacity to give informed consent or in emergency treatment situations. It is recognised that for some patients, especially those in the pre-operative setting, it may be difficult to pre-empt whether a transfusion will be required during the procedure [13] (i.e. from the time the procedure starts and the patient loses capacity to give consent through to the time the patient recovers capacity, and so may include the post-operative period where the patient may remain under sedation).

Patients often have to assimilate large volumes of information relevant to their condition and treatment options, and so providing additional information on the indications, benefits, risks and alternatives to transfusion where it is unlikely to occur could be deemed not only unnecessary but may also be detrimental to the patient, resulting in information overload and a risk that information related to other risks may be missed. In line with this principle, we recommend that, where appropriate, consent to receive a blood transfusion is incorporated into the consent form for the procedure.

We recommend that potential recipients of blood are considered in one of six groups:

- The patient is **unlikely** to receive a transfusion as part of a procedure during which time the patient will be incapacitated. For example, during most types of surgery where no blood is routinely requested prior to surgery and no 'group and save' sample is taken pre procedure. The patient should be informed that transfusion is unlikely unless an unexpected emergency arises. Advance care planning is essential for this category of persons. The health care practitioner should ascertain whether the patient would consent to receive a transfusion under such circumstances and only provide additional information about the transfusion as required/requested by the patient. That this discussion has occurred should be documented contemporaneously in the patient's clinical record. If the patient does receive a

transfusion, the patient will need to be informed post procedure prior to discharge and retrospective patient information will be required.

- The patient will **possibly/is likely** to receive a transfusion as part of a procedure during which time the patient will be incapacitated. This will be for individual clinicians to determine, but may be defined, for example, as requesting a 'group and save' sample. Inform the patient that transfusion is possible/likely. Provide a general explanation of the procedure, along with an explanation of the risks inherent in the procedure and the risks inherent in refusing the procedure. Complete the informed consent for transfusion process, documenting in the patient's clinical record that this shared decision-making process has occurred, and that the patient has provided consent. If the patient does receive a transfusion, the patient will need to be informed post procedure prior to discharge.

- The patient will **definitely** receive a transfusion. Complete the informed consent for transfusion process, documenting in the patient's clinical record that this shared decision-making process has occurred and the patient has been informed of the risks and benefits of a recommended course of action (as well as other options) and has provided consent.

- The patient needs to receive a transfusion in an **emergency** and is unable to provide consent. This must be documented in the patient's clinical record and the patient will need to be informed post-emergency (when the patient is deemed to have capacity) and retrospective patient information will be required. If the patient is known to have previously refused transfusions this must be managed appropriately.

- The patient is expected to receive **multiple** transfusions on more than one occasion, for example patients with haemoglobinopathy or haematological conditions. Long-term multi-transfused patients will need ongoing information about risks, benefits and any potential alternatives. Long-term issues related to transfusion may include alloimmunisation and iron overload. This is discussed further in 'Duration of Consent'.

- The patient who **refuses** blood transfusion. Their wishes should be respected with relevant guidelines followed.

Patients may move between any of these groups during their admission.

Documentation of Consent

The 2011 SaBTO Consent for Transfusion recommendations [1] did not require signed consent by the patient. Instead it was recommended that the verbal consent provided by the patient should be recorded in the patient's records by the healthcare professional. The emphasis should be on the shared evidence-based dialogue and decision-making element of the consent process, rather than on obtaining the patient's signature. This recommendation has not been changed, although it should be recognised that this is the minimum requirement, and individual organisations may choose to implement consent signed by the

patient. Where consent forms include a 'tick box', these should be formatted in a way which supports valid and informed consent, and we suggest that the patient initials the box to indicate informed consent.

Recommendation: Informed and valid consent for transfusion should be obtained and documented in the patient's clinical record by the healthcare professional.

Duration of Consent

For all patients, clinicians should consider how long the consent for transfusion remains valid. We will consider this under two patient groups:

- Short-term consent - For example, where consent is obtained at the start of a patient's admission, as part of a procedure specific consent, or pre-operatively, where transfusions may be required at various points during that admission.
- Long-term consent – For example, long-term multi-transfused patients with haemoglobinopathy or other haematological conditions, where transfusions are administered over successive admissions or out-patient treatments.

There are too many variables and individual patient scenarios for SaBTO to provide definitive guidance. We suggest that this needs to be discussed and agreed with the patient as part of the shared decision-making process, and in line with local policies. If it is deemed appropriate that consent may span more than one transfusion episode, or across the duration of a patient admission period, this should be documented in the patient's clinical notes. Verbal agreement to the transfusion should be obtained from the patient at the time of each transfusion episode. Be mindful that patients can change their mind at any point before the procedure. If the patient changes their mind, they are entitled to withdraw their previous consent. Recognise that seeking of consent is more than a signature on a form. It is the process of providing the information that enables the patient to understand (and in some cases accept) risk and make a decision to undergo a transfusion. This was found in the recent case of Thefaut v Johnston [2017] EWHC 497 [14] Green J observed that: 'It is accepted that the simple fact that Mrs Thefaut signed the hospital consent form is not to be taken as an indication of acceptance of risk. In my view the document is of no real significance on the present facts. (It would have greater significance in emergency cases involving no prior contact between patient and clinician)'.

Consent should be considered informed decision making that assists the patient to decide whether to consent to a particular intervention, whilst respecting their right to autonomously decide how they wish to proceed.

Recommendation: For long-term multi-transfused patients, we recommend that written consent be given at least annually.

Information after transfusion (Retrospective Information)

The provision of retrospective information falls into two main categories:

- Patients who lacked capacity to receive information and to provide informed and valid consent pre-transfusion but regain capacity post-transfusion (e.g. emergency transfusions)
- Patients who were told pre-procedure (e.g. pre-operatively) that they *might* require a transfusion as part of that procedure. These patients must be informed that they received a transfusion.

The provision of retrospective information is important to ensure not only that patients are informed of any associated potential risks relating to transfusion, but also to ensure that patients are aware that because they have received a blood transfusion, they are no longer eligible to donate blood.

This retrospective information should be provided to the patient when they are deemed to have capacity and are therefore able to understand the implications of having received a blood transfusion. In order to ensure that all patients are informed before their discharge from hospital, it is recommended that this should become part of the patient discharge procedure. In addition, for all patients, discharge documentation to the patient's GP should contain details related to transfusion, including any adverse events associated with the transfusion.

Recommendations:

Patients who have a blood transfusion and who were not able to give informed and valid consent prior to the transfusion should be informed of the transfusion details and provided with relevant written information prior to discharge.

All patients who have received a transfusion should have details of the transfusion included in their hospital discharge summary to ensure the GP is aware.

Information resources for patients and public

The provision of written information to patients can help assist the consent process by facilitating the opportunity for the patient to digest, recapitulate and reaffirm their decision. Patient information leaflets which summarise the main risks and benefits of the transfusion can be useful to help patients understanding and recall of this information. Such information leaflets can only provide generic information and do not take into account individual patient circumstances, conditions, values or priorities. They are only intended to support and reinforce verbal information and discussion.

Patient information leaflets are freely available from each of the UK Blood Services. The UK Blood Services are currently considering the development of a standardised patient

information leaflet across the whole of the UK, plus an additional on-line information resource for patients and the wider public.

Where other organisations provide information related to transfusion (for example NHS Choices, or patient support organisations such as Sickle Cell, Thalassaemia or other haematology support groups) these organisations should work cooperatively with the UK Blood Services to ensure relevant up-to-date information is included.

Recommendation: The UK Blood Services should provide a standardised source of information for patients who may receive a blood transfusion in the UK.

Information resources and training for healthcare professionals

In order to provide informed and valid consent for transfusion, it is vital that all healthcare professionals involved in the transfusion process are supported to maintain their knowledge of consent and its relevance and importance in blood transfusion.

There have been considerable advances since the 2011 SaBTO Patient Consent for Blood Transfusion recommendations (see above). The General Medical Council (GMC) *Good Medical Practice* [15]is the core guidance for all registered doctors and all other GMC guidance builds on these core principles. The GMC *Promoting Excellence* [16]sets out standards which are key requirements for the management and delivery of undergraduate and postgraduate medical education and training in the UK with the focus on patient safety. *The Code* [17] from the Nursing and Midwifery Council (NMC) provides professional standards of practice and behaviour for nurses, midwives and nursing associates in the UK, and the NMC *Realising Professionalism: Standards for Education and Training* provide a framework for nursing and midwifery students [18]. Patient safety is central to these standards.

The British Society for Haematology (BSH 2017) [19] recommends that all staff should receive regular (minimum three yearly) knowledge and skills training in blood transfusion for all of the processes they are involved in. The www.learnbloodtransfusion.org.uk e-learning package now has a module specific to consent and blood transfusion.

However, it is recognised that there is a continued need to support healthcare professionals maintain their knowledge and the SaBTO Consent working group has considered that a centralised UK wide (on-line) information resource would be beneficial to help support consent for transfusion discussions.

Recommendations: Training in consent for transfusion should continue to be included in all relevant undergraduate healthcare professionals training, followed by continuous, regular knowledge updates (minimum 3-yearly) for all healthcare professionals involved in the consent for transfusion process.

There should be a centralised UK wide information resource for healthcare professionals to facilitate consent for transfusion discussions, indicating the key issues to be discussed when obtaining informed and valid consent for a blood transfusion, and providing up-to-date information on the risks of transfusion. This resource should be provided by the UK Blood Services. The feasibility of developing and maintaining this resource should be completed by the UK Blood Services within 6 months of the publication of these recommendations.

Monitoring compliance

The National Comparative Audit (NCA) of Patient Information and Consent (2014) [10] indicates that the implementation of consent for transfusion was sporadic and compliance was generally low. Future NCA's should include consent for transfusion (where appropriate) to continue to provide compliance data and identify areas for improvement.

Compliance to these recommendations should be checked by independent health regulators as part of their regulatory inspections. Improvements in the process and enhancing the quality of care provided can also be supported by commissioning frameworks, such as the Commissioning for Quality and Innovation (CQUIN) framework for England (or equivalent in devolved countries). Care Quality Commission (CQC, or equivalent in devolved countries) inspections could regularly cover transfusion practice to ensure fundamental standards are met and identify areas for improvement.

Recommendations: Compliance with these SaBTO Consent for Transfusion recommendations should be monitored by regulators.

All UK Healthcare organisations who provide blood transfusions should employ mechanisms to monitor the implementation and compliance with these SaBTO recommendations, which should be overseen by the appropriate Regulatory Bodies.

References

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(https://www.infectedbloodinquiry.org.uk/sites/default/files/Terms-of-Reference-Infected-Blood-Inquiry.pdf

[4] General Medical Council (GMC) *Good Medical Practice*
https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice

[5] Advisory Committee on Dangerous Pathogens. Prevention of CJD and vCJD by the Advisory Committee on Dangerous Pathogens' Transmissible Spongiform Encephalopathy (ACDP TSE) subgroup. https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group

[6] National Institute for Care and Health Excellence. Blood Transfusion Guideline NG24
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[7] National Institute for Health and Clinical Excellence. Blood transfusion Quality standard [QS138] https://www.nice.org.uk/guidance/qs138

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[14] 2 Hare Court. Thefaut v Johnston [2017] EWHC 497: https://www.2harecourt.com/training-and-knowledge/thefaut-v-johnston/

[15] General Medical Council. Good medical practice. https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice

[16] General Medical Council (GMC) *Promoting Excellence* https://www.gmc-uk.org/education/standards-guidance-and-curricula/standards-and-outcomes/promoting-excellence

[17] Nursing and Midwifery Council (NMC) *The Code* https://www.nmc.org.uk/standards/code/

[18] Nursing and Midwifery Council (NMC) *Realising Professionalism: Standards for Education and Training* https://www.nmc.org.uk/standards-for-education-and-training/

[19] British Society for Haematology (2017) https://b-s-h.org.uk/guidelines/guidelines/administration-of-blood-components/

Appendix 1 - SaBTO Consent for Transfusion Working Group members

Name	Professional role/affiliation	Membership role
Andrea Harris	Diagnostic & Therapeutic Services Professional Nursing Lead, NHSBT	Working Group Chair
James Neuberger	Liver Transplant Physician	SaBTO Chair
Damien Carson	Consultant Anaesthetist, The Ulster Hospital	Northern Ireland Transfusion Committee
Roger Graham	Lay Organ Representative	Lay Organ Representative
Mike Murphy	Professor of Transfusion Medicine, University of Oxford and Consultant Haematologist, NHSBT and Oxford University Hospitals NHS Foundation Trust	Transfusion Medicine Specialist
Charles Baker	Clinical Director Anaesthesia, Intensive Care & Theatre Specialist, University Hospitals of North Midlands NHS Trust	National Blood Transfusion Committee: Patient Involvement Working Group
Megan Rowley	Consultant in Transfusion Medicine Scottish National Blood Transfusion Service	Scottish National Blood Transfusion Service
Rhonda Skeete	NBTC Patient representative	Patient Perspective
Ann Benton	Consultant Haematologist, Welsh Blood Service	Welsh Blood Service
Shruthi Narayan	SHOT Medical Director	SHOT Medical Director