# **CONSULTATION ON**

# SaBTO Patient Consent for Blood Transfusion

# **DRAFT Recommendations 2020**

# Please return completed form to SaBTO mbsabto@dhsc.gov.uk by 10<sup>th</sup> July 2020

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Name of Organisation (if appropriate) Royal College of Physicians of Edinburgh

Role (if appropriate) Acting President

1. Is there anything in the document that is unclear? No X / Yes  $\Box$ 

If Yes, please give details

2. Is there anything in the document that you think is incorrect? No X / Yes  $\Box$ 

If yes, please give details

# 3. Response to Recommendations

# **Recommendation:**

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.

Do you agree with this recommendation	№ 🗆	yes X

# If No, please explain why

College Fellows agreed that a PIL does not need to be given at this stage but should be available for those who ask.

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.

Do you agree with this recommendation NO I YES X	Do you agree with this recommendation	NO 🗆	yes X
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# If No, please explain why

This is supported by College Fellows with an additional comment that consideration should be given to providing a patient information leaflet at this stage

# **Recommendation:**

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.

Do you agree with this recommendation	№ 🗆	yes X
If No, please explain why		

#### **Recommendation:**

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 postemergency (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.

# If No, please explain why

Colleagues felt that this recommendation needs to be more carefully and explicitly worded to suggest proceeding with transfusion and seeking retrospective consent <u>if there is no reason to</u> <u>believe that the patient would refuse transfusion</u>. If a patient who is unable to give consent has previously refused transfusion and there is evidence, such as an advanced directive, or reason to believe that he/she would not want transfusion, actions taken and rationale should be documented.

#### **Recommendation:**

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'.

Do you agree with this recommendation	№ 🗆	yes X
If No, please explain why		

Recommendation:				
The patient who <b>refuses</b> blood transfusion. Their wishes should be respected with relevant guidelines followed.				
Do you agree with this recommendation NO I YES X				
If No, please explain why				
Although this recommendation was supported, College Fellows asked whether it applied only to adult patients and felt that a comment about paediatric patients, including specific age of paediatric patient, was required. It should also state that wishes of all refusing blood should be clearly and accurately documented.				

#### **Recommendation:**

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

Do you agree with this recommendation		yes X
If No, please explain why		
Clarification would be helpful about whether there s documentation in the medical notes that reasons fo have been discussed with the patient.	· · · · · · · · · · · · · · · · · · ·	

For long-term multi-transfused patients, written consent should be given at least annually.

Do you agree with this recommendation	NO X		
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# If No, please explain why

Colleagues felt that annual consent was not necessary but ongoing discussion with patients about their condition, any changes in condition and any changes in the risks/benefit ratio for blood transfusion was part of their care and should be clearly documented in their notes. An example given was:

"For patients on a chronic transfusion programme, for example those with transfusion dependent myelodysplasia or haemoglobinopathy, consent is implied by the patient's willingness to continue to attend for regular transfusion".

# **Recommendation:**

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.

Do you agree with this recommendation	№ 🗆	yes X
If No, please explain why		

# **Recommendation:**

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

Do you agree with this recommendation	NO 🗆	yes X
If No, please explain why		
It was noted by Tissues, Cells and Organ donation co deceased tissue and organ donor medical reviews.	lleagues that this would	d be beneficial in

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

Do you agree with this recommendation	№ 🗆	yes X
		YESA

# If No, please explain why

College Fellows supported this but felt that it generally took a long time to update and publish PILs and therefore working across all 4 blood services might slow the process down. Scottish National Blood Transfusion Service (SNTBS) has already started co-operating with other blood services to produce a common standardised PIL and are committed to this approach.

It was also suggested, if a national patient information leaflet is agreed, this could be updated following the annual SHOT report and could be an ideal time to re-consent regularly transfused patients based on these updated findings.

# **Recommendation:**

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.

Do you agree with this recommendation	NO 🗆	yes X	
If No, please explain why			

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.

# If No, please explain why

Although supported, the practicalities and timeline for of this recommendation were questioned, partly because of the COVID-19 pandemic and partly because of the central organisation and coordination required, particularly if needed to be standardised across the UK. Clarification was requested as to whether this was to be electronic, paper-based, or available and updated by other means.

As regards frequency of updates, it was felt that annually would be sufficient, otherwise printing and document control would be difficult to maintain and co-ordinate. As with the PIL, this could be updated following the annual SHOT report.

# **Recommendation:**

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

Do you agree with this recommendation	ΝΟ Χ		
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#### If No, please explain why

There was a general lack of support for this recommendation by Fellows for a number of practical reasons. Some supported the principle but felt local monitoring was the only practical solution. The hospitals in Scotland who administer transfusion are not normally inspected by regulatory bodies and transfusion is primarily a clinical activity so not covered by UKAS for example. On the other hand the blood establishments, who are inspected by the regulators, don't have control on what happens in the hospitals and could lead to repeated incidents for the blood establishments that they may not be able to influence.

Additionally from the practical point of view, would a regulator plan punitive action, if these recommendations were not rigorously followed? What punitive measures would you put in place? Who would set targets and what targets would be set? Would regional variation in data collection allow this approach?

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.

Do you agree with this recommendation	№ 🗆	yes X	
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# If No, please explain why

The blood services could be audited on their provision of appropriate information resources as suggested above. Responsibility for monitoring compliance with these regulations would lie more within hospital board governance structures.

# Any other comments?

College Fellows are broadly supportive of these recommendations but colleagues, all with a clinical background, have a number of practical suggestions as to the feasibility of some of the resources required and these have been indicated in the relevant boxes.

The annual review of consent for transfusion in patients on long term transfusion was not supported but not because of the principle, rather that this should be an ongoing conversation and should be guided by change in risk or change in the patient's treatment regime, as and when it was deemed clinically appropriate.

The other area which caused concern was external/national regulation of consent – largely because it could become the responsibility of organisations that were not in direct control of local practice who would have no influence over corrective action.

# Thank you

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