CONSULTATION ON

SaBTO Patient Consent for Blood Transfusion

DRAFT Recommendations 2020

Please return completed form to SaBTO mbsabto@dhsc.gov.uk by 10th July 2020

Name of person completing form Paula Bolton-Maggs

Contact Details (optional)

Name of Organisation (if appropriate) The Royal College of Pathologists

Role (if appropriate) Chair, Transfusion Medicine Specialty Advisory Committee

1. Is there anything in the document that is unclear? No ☐ / Yes ☒

If Yes, please give details.

In the summary:

Where does SD-FFP sit? Is this a medicine or a blood component?

'Risks inherent in the procedure' is a bit confusing. Is the transfusion the procedure?

Health care practitioner or professional? Both terms are used and ought to be consistent. What qualifies the HCP to obtain consent?

4th bullet point add 'explain the risks'

Page 2: Audit of compliance: which regulatory authorities and how will this be done?

2. Is there anything in the document that you think is incorrect? No ☐ / Yes ☒

If yes, please give details

'Group and save' should be changed to 'group and screen'

The reference to the transfusion choosing wisely statements should be changed to the full list which is here: https://www.rcpath.org/profession/patient-safety-and-quality-improvement/patient-safety-resources/choosing-wisely/recommendations-for-transfusion-medicine.html

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	**NO** ☒	**YES** ☐

If No, please explain why.
Need to ensure that patient has been given sufficient opportunity to ask questions about risks. 'Have you any worries?'

Recommendation:
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** ☐	**YES** ☒

If No, please explain why

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	**NO** ☐	**YES** ☒

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 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.		
Do you agree with this recommendation	**NO** ☐	**YES** ☒
If No, please explain why		

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	**NO** ☐	**YES** ☒
If No, please explain why		

Recommendation: The patient who **refuses** blood transfusion. Their wishes should be respected with relevant guidelines followed.		
Do you agree with this recommendation	**NO** ☒	**YES** ☐
If No, please explain why Need to specify that they have mental capacity to make that decision		

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	**NO** ☐	**YES** ☒
If No, please explain why		

Recommendation: For long-term multi-transfused patients, written consent should be given at least annually.		
Do you agree with this recommendation	**NO** ☐	**YES** ☒
If No, please explain why		

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	**NO** ☐	**YES** ☒
If No, please explain why		

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	**NO** ☐	**YES** ☒
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** ☐
If No, please explain why – In addition the patient should be given written information about the transfusions received to include dates. I am not at all sure GPs read all the text in discharge summaries.		

Recommendation: 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	**NO** ☐	**YES** ☒

If No, please explain why

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** ☒
If No, please explain why		

Recommendation: 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.		
Do you agree with this recommendation	**NO** ☐	**YES** ☒
If No, please explain why		

Recommendation: Compliance with these SaBTO Consent for Transfusion recommendations should be monitored by regulators.		
Do you agree with this recommendation	**NO** ☒	**YES** ☐
If No, please explain why See below as well as this: PBM has been trying through SHOT and my role as a specialist advisor to get the CQC engaged with this but they generally think of transfusion as laboratory-based and have not really taken it on board		

Recommendation: 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	**NO** ☒	**YES** ☐
If No, please explain why – 'Regulatory bodies' is too vague.		

Any other comments?
A summary of further comments from the RCPath Specialty Advisory Committee on Transfusion Medicine:

- All members support and think guidance is fair, well worded and clear.
- All the other comments are around logistics and implementation:
    - National Pre-operative consent form should have clear guidance and 'tick box' for recommendations.
    - The method for documenting, and retaining annual consent, for patients on lifelong / regular transfusions should be clarified.

Comment from the Chair of the Specialty Advisory Committee on Transfusion Medicine:

'On a personal level I think an electronic solution should be sought / recommended. I am not clear how 'regulatory bodies' will police this nor what the penalties may be for 99% compliance – but practically if you are running a paper based system it will be difficult to retrospectively find the evidence of 'informed' consent and the quality will vary. If we are to achieve good consent there needs to be standard national wording for each of the scenarios on a consent form that the patient needs to sign which is then scanned to the BT lab computer and retained with all the other records of transfusion.'

Additional comments from a Transfusion Medicine colleague:

'I think that a major change about consent was always going to be a necessary outcome from the Infected Blood Inquiry. The majority of the recommendations are worded so that it would be difficult to object to them, but of course the detailed implementation is the challenge. The deeper point is that consent is generally poor for most medical interventions. Practically, this has implications for the training recommendations. I would support increased training for consent, of which transfusion would be a part, but am fearful of a proliferation of separate "consent frameworks" for every procedure and discipline.

The recommendation for Blood Services to provide a central information resource has analogies with pharmacology companies providing drug safety information and I am reminded of the terrifying list of side effects which come with medicines insert leaflets. Should this resource also include information about the benefits of transfusion? For me, quantifying the benefits of transfusion is much harder than quantifying the risks. Done well, this could have a major effect on transfusion safety, reducing unnecessary transfusions and encouraging patients to be involved with identity checks.

Sadly, I think the recommendation that consent should be monitored by regulators will indeed be necessary to stimulate change. But it will also have the effect of shaping the nature of that change. The danger of course is that what will emerge is a system with the primary purpose of showing documentation to regulators, while the really difficult consent problem of establishing whether the recipient has understood the balance of risks and benefits will remain unsolved.'

Thank you

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