

SaBTO

Advisory Committee on the Safety of
Blood, Tissues and Organs

PATIENT CONSENT FOR BLOOD TRANSFUSION

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SaBTO RECOMMENDATIONS ON CONSENT FOR BLOOD TRANSFUSION

As an outcome of a public consultation in 2010, a series of recommendations were proposed and supported by the SaBTO committee regarding patient consent for blood transfusion, which are set out below.

Process

The GMC already has a generic standard for consent and this does not need to be re-invented for blood transfusion.

Recommendation:

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

Recommendation:

There should be a modified form of consent for long term multi-transfused patients, details of which should be explicit in an organisation's consent policy.

Recommendation:

There should be a standardised information resource for clinicians indicating the key issues to be discussed by the healthcare professional when obtaining valid consent from a patient for a blood transfusion.

Governance

There is a need to strengthen the governance and oversight of consent for blood transfusion and this can be achieved by the following:

Recommendation:

The consent standard developed by Health Improvement Scotland (formerly NHS Quality Improvement Scotland) should be adopted throughout the UK for consent for blood transfusion. (Ref 4)

Recommendation:

The Care Quality Commission (CQC), NHS Litigation Authority (NHSLA) and equivalent organisations in Northern Ireland, Scotland and Wales should be aware of the consent standard for blood transfusion recommended by SaBTO.

Recommendation:

A UK comparative audit of consent for transfusion should be carried out, facilitated by the National Comparative Audit of Blood Transfusion (a collaborative between the Royal College of Physicians and NHS Blood and Transplant).

Recommendation:

Depending on the role envisaged for Healthwatch, the potential role of patient groups in providing active oversight should be explored.

Patient information

The UK Blood Services have a key role in ensuring standardisation and availability of patient information.

Recommendation:

There should be a standardised source of information for patients who may receive a transfusion in the UK.

Recommendation:

Patients who have received a blood transfusion and who were not able to give valid consent prior to the transfusion should be provided with information retrospectively.

Recommendation:

SaBTO consent working group should produce good practice guidance to help identify the most effective way of providing information retrospectively when patients were unable to give prior consent.

Patient and Public Education

The UK Blood Services have a key role in helping to educate patients and the public about the risks, benefits and alternatives to blood transfusion:

Recommendation:

UK Blood Services should have an ongoing programme for educating patients and the public about blood transfusion as part of their respective 'Better Blood Transfusion' strategies.

Professional Education

There is a need to support healthcare professionals to improve their knowledge of consent and its relevance and importance in blood transfusion.

Recommendation:

Use of the www.learnbloodtransfusion.org.uk e-learning package should be promoted by the UK Blood Services and Royal Colleges for all staff involved in the blood transfusion process.

Recommendation:

The UK Better Blood Transfusion Network should explore the feasibility of developing a new module specific to consent and blood transfusion as part of its 2012/13 work plan.

Recommendation:

Completion of the www.learnbloodtransfusion.org.uk e-learning package should be included in all undergraduate curricula. Reference to consent for blood transfusion should be included in the undergraduate curriculum as part of the learning objectives outlined for the principles of consent.

An action plan to support the delivery of these recommendations has been approved by SaBTO and is available to download from the Better Blood Toolkit on the UK Blood Transfusion & Tissue Transplantation Services website www.transfusionguidelines.org.

The Better Blood Transfusion Toolkit also contains details of the consent for transfusion standard recommended for use by SaBTO and a copy of good practice guidance for giving retrospective information produced by the SaBTO consent working group.

BACKGROUND

It is a general legal and ethical principle that valid consent should be obtained from a patient before they are treated. The General Medical Council (GMC) has published guidance on consent (Ref 1). The 2000 NHS Plan pledged that informed consent must be sought from all NHS patients and research subjects (Ref 2). To help achieve this the Department of Health set up the Good Practice in Consent initiative and published a national guidance framework for consent (Ref 3). However, as blood transfusion is often an additional procedure during a course of treatment, there was no specific guidance given for blood transfusion.

Audits presented to SaBTO have identified that the practice of obtaining any form of valid consent for blood transfusion is highly variable in the UK. This was also confirmed by the European Blood Alliance in a survey of its members in 2008 on "Consent to transfuse" (unpublished).

The following issues have been identified by SaBTO:

- Patients are not always given information on the risks, benefits, and alternatives to transfusion, or the right to refuse transfusion
- Patients are not always made aware that they have received a transfusion
- Patients who are unaware that they have received a transfusion may go on to donate blood when they should not
- There is inconsistent practice across the UK.

CONSULTATION PROCESS

In March 2010 SaBTO initiated a public consultation on patient consent for blood transfusion through the Department of Health website. The purpose was to consult widely on the options for undertaking consent for blood transfusion and the potential operational challenges if documented consent were to be mandated.

The consultation had the following key objectives:

- Identify the preferred option for recording consent
- Explore the potential operational impact of implementing a standardised form of consent for transfusion
- Confirm what type of information patients should receive.

The consultation ran from 3rd March until 27th May 2010. Online surveys were available for both healthcare professionals, patients and individuals with an interest in patient safety. The consultation was successfully promoted at a number of key meetings including the Chief Medical Officer's National Blood Transfusion Committee (and equivalent groups in Northern Ireland, Scotland and Wales) and by members of the UK Better Blood Transfusion Network.

SUMMARY OF RESPONDENTS

The total number of responses received was 943 broken down as follows:

- 875 healthcare professionals
- 59 with an interest in patient safety
- 9 Royal Colleges.

The healthcare professional respondents included anaesthetists, surgeons, obstetricians, haematologists, transfusion practitioners and nurses. Those responding with an interest in patient safety included individual patients, patient associations, hospital governors and risk managers. There was a good distribution of responses to the questionnaire from across the whole of the UK.

SUMMARY OF RESPONSES

The results of the survey were fully analysed by a consent sub-group of the main SaBTO committee. Responses to the consultation primary objectives are summarised below.

Key Objective One: Identify the preferred option for recording consent

95% of healthcare professionals and 98% of patient safety respondents agreed that patients should be given the opportunity to consent to a blood transfusion. However, healthcare professionals were equally divided (50%) on whether the consent should be compulsory or not.

88% of healthcare professionals identified that they use either local or national guidance for consent and 72% thought that this was adequate for their needs.

The development of a modified form of consent for the long-term multi-transfused patient groups was supported by 70% of healthcare professionals.

68% of healthcare professionals agreed that consent for a blood transfusion should remain as outlined by the GMC, namely recorded by the healthcare professional in the patient's clinical notes. There was a divergence of opinion on whether this should be co-signed by the patient; 51% of the respondents to the patient safety questionnaire indicated that consent should be recorded by the healthcare professional and signed by the patient.

Key Objective Two: Explore the potential operational impact of implementing a standardised form of consent for transfusion

46% of respondents expressed that the main operational challenge to obtaining valid consent was lack of resources; this included issues such as hospital finances, staff numbers and workload.

35% of respondents thought that patient factors would provide an operational challenge, such as a patient's level of understanding of the information presented to them, whether the information for the patient would lead to more anxiety about a procedure, or whether the patient would suffer from information overload.

34% of healthcare professionals identified that raising patient awareness would be the preferred approach to minimising the operational impact, for example by providing patients with an informed discussion of risks, benefits and alternatives prior to treatment. There was strong support for supplementing this with an information sheet or a patient leaflet explaining the risks and benefits of a blood transfusion.

Key Objective Three: Confirm what type of information patients should receive

Respondents from both groups highlighted that the most important issues to be discussed with patients were:

- reasons for transfusion
- risks of transfusion
- benefits of transfusion
- consequences of transfusion
- alternatives to transfusion.

Almost half of the healthcare professionals (49%) thought that any qualified healthcare professional should be able to take valid consent and this was in agreement with those responding to the patient safety questionnaire (56%). There was strong support for consent being taken prior to treatment, or at the earliest opportunity following an emergency.

A majority of both healthcare professionals (72%) and patient safety respondents (82%) considered that patients should receive information in a discussion with the healthcare professional and also in a written format appropriate to the patient's needs.

82% of healthcare professionals agreed that a generic information resource to assist discussions on consent for transfusion would be helpful. The majority thought that this should only be used as an aide memoire and its use should not be compulsory.

The great majority of both healthcare professionals (80%) and those with an interest in patient safety (98%) believed it is necessary to give patients information retrospectively when they have received a transfusion as an emergency, without an opportunity to give valid consent beforehand.

26% of healthcare professionals identified that practical challenges to providing retrospective information lie in appropriately addressing patients' concerns. These include the timing of the provision of information to patients after the event, and ensuring that the patient is fit and well enough to understand the information. Concerns that patients might not receive the appropriate information, including on risks and benefits, were expressed by 17% of healthcare professionals.

In addition, 21% of healthcare professionals highlighted that staffing issues presented challenges for ensuring retrospective information was delivered to patients. This included identifying a responsible person for this role and staffing levels within NHS trusts.

20% of healthcare professionals highlighted that keeping the patient well informed through a variety of different media will help to overcome the main challenges to providing retrospective information.

Summary

The overall viewpoints expressed by respondents to this consultation were that there is a need for:

- ensuring that best practice as outlined by the GMC is followed
- a modified form of consent for long-term multi transfused patients, which should be reviewed on a regular basis with patients
- a generic information resource for healthcare professionals to assist discussions on consent for transfusion
- standardised patient information leaflets in the UK
- retrospective information for patients who have received a blood transfusion
- improved training on consent and its relevance in transfusion for clinical staff to inform discussion with patients during the consent process.

APPENDIX 1 : SaBTO CONSENT WORKING GROUP MEMBERS

Dr Shubha Allard – Consultant Haematologist, Barts & The London NHS Trust/ NHS Blood and Transplant

Dr Emma Court - Surgical CT2, Upper Gastrointestinal Surgery, Southampton University Hospital NHS Trust

Dr Yasmin Drabu – Senior Medical Officer (secondee), Infectious Diseases and Blood Policy, Department of Health

Andrea Harris - Better Blood Transfusion Regional Lead - Midlands & South West, NHS Blood and Transplant

Fran Hartley - Transfusion Practitioner, Leeds Teaching Hospitals NHS Trust

Catherine Howell (Chair) – Chief Nurse Patient Services, NHS Blood and Transplant/SaBTO member

Elwyn Nicol – Patient representative/SaBTO member

Professor Jo Martin – Director of Academic Health Sciences, Barts and The London School of Medicine and Dentistry and NHS Trust/ SaBTO Member

Dr Derek Norfolk – Consultant Haematologist, Leeds Teaching Hospital NHS Trust/NHS Blood and Transplant

Douglas Watson – Clinical Effectiveness Co-ordinator, Scottish National Blood Transfusion Service

The work of the SaBTO Consent Working Group was supported by members of the Health Protection Analytical Team, Department of Health

REFERENCES

- 1) Consent guidance: patients and doctors making decisions together. General Medical Council June 2008.
- 2) The NHS Plan: a plan for investment, a plan for reform. Department of Health, 2000.
- 3) Reference guide to consent for examination or treatment, 2nd edition 2009, Department of Health (Gateway ref 11911).
- 4) Clinical Standards: Blood Transfusion. NHS Quality Improvement Scotland 2006. ISBN 1-84404-427-0