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**Specific Informed Consent for Blood Transfusion:
The Ethical Considerations**

National Advisory Committee on Bioethics

**Department of Health
January 2013**

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Preface

The Minister for Health, Dr. James Reilly T.D., established the National Advisory Committee on Bioethics in March 2012. The task of this Committee is to advise the Minister on the ethical and social implications of scientific developments in human medicine and healthcare. In particular, this includes:

1. Providing advice in the form of expert reports on priority issues of national significance as requested by the Minister.
2. Providing recommendations and assistance towards the development of healthcare policy and associated legislation.
3. Representing Ireland at international fora on bioethics and collaborating, communicating and exchanging information with other national bioethics committees regarding developments in health policy.

In May 2012 the Minister requested that the Committee consider the question of whether specific consent for blood transfusion was required. This was on foot of correspondence from the Irish Blood Transfusion Service in relation to this matter. In order to assist the Department's thinking on this issue, the Minister sought the advice of the Committee.

This opinion document represents the culmination of the Committee's deliberations on the issue of specific informed consent for blood transfusion.

Introduction

Practical Overview of Blood Transfusion

Blood transfusion which involves providing blood previously donated by one individual to another individual is referred to as allogeneic transfusion. Autologous transfusion involves the collection of blood from an individual and re-transfusing it back to him/her, which may include blood salvaged during a surgical operation.

The whole blood that is donated is separated into its constituent parts for transfusion, i.e. red blood cells (referred to as red cell concentrates), platelets and plasma. The transfusion of red cell concentrates may be clinically indicated for a number of reasons, including: the loss of blood due to surgery or injury; the side-effects of chemotherapy; anaemia (including anaemia during pregnancy); and haemoglobinopathies (genetic conditions, which prevent the body from forming proper blood cells).¹ Platelet transfusion may be required for individuals with leukaemia or clinically low platelet counts. Plasma may be required for individuals with clotting difficulties, although it should be noted that plasma from Irish donors has not been given to patients since 2001 due to the risk of transmitting variant Creutzfeldt-Jakob disease (vCJD).^{2,a}

Transfusions are, therefore, relatively common medical procedures, for example, an estimated 70,000 people will have transfusions in Irish hospitals this year.³ In the UK approximately 2.5 million units of blood are transfused annually.⁴ Blood transfusion is considered to be the most frequently performed hospital procedure in the US.⁵

The Irish Blood Transfusion Service (IBTS) is responsible for the collection of blood donations and the processing and distribution of blood products. The EU *Directive 2002/98/EC* outlines particular requirements for the processing of blood supplies and sets out standards for blood establishments (such as the IBTS), which include responsibilities, personnel, quality management, documentation, record keeping, traceability, adverse events, donor management, testing of donations, storage and transport.⁶ The Directive states that “in order to safeguard public health and to prevent the transmission of infectious diseases, all precautionary measures during their collection, processing, distribution and use need to be taken making appropriate use of scientific progress in the detection

^a In exceptional cases white blood cells may be transfused to critically ill patients with bone marrow failure following chemotherapy.

and inactivation and elimination of transfusion transmissible pathogenic agents". In addition, EU *Directive 2004/33/EC* sets out technical requirements for blood and blood products in all Member States and defines some of the aforementioned standards.⁷ Both of these Directives have been transposed into Irish law in Statutory Instrument No. 360 of 2005.⁸

Safety Considerations and Risks

The utilisation of specific precautionary measures and safeguards has greatly improved the safety of transfusion internationally. For example, in line with regulations and best practice, the IBTS has implemented numerous measures to improve the safety and reduce the risks associated with the blood supply, including:

- Deferral and selection criteria to exclude potential donors who may be at higher risk of transmitting an infectious agent, such as vCJD, malaria, Dengue Fever and West Nile Virus.
- Typing all donated blood for ABO and Rhesus blood system compatibility.
- Testing all donated blood for HIV, Hepatitis B, Hepatitis C, human T-lymphotropic virus I/II and syphilis using serology tests and nucleic acid testing.
- Processing blood after collection, e.g. through universal leucodepletion (removing the white blood cells) and viral inactivation of certain blood products.

As a result, currently in Ireland the risk of viral transmission from donated blood is estimated as 1 in 750,000 units of blood transfused for Hepatitis B, 1 in 9 million units transfused for HIV and 1 in 20.7 million units transfused for Hepatitis C.⁹ In the UK the risks are 1 in 670,000 for Hepatitis B, 1 in 5 million for HIV and 1 in 83 million for Hepatitis C.⁴ Indeed, blood transfusion is considered by many to be safer now than at any previous time.

However, despite the improved safety, blood transfusion, like any medical intervention, is not completely risk free. Notwithstanding the risk of transfusion-transmitted viral infection already discussed, there are a number of other risks associated with blood transfusions, which include:¹⁰

- Septic Reaction - due to bacterial contamination.
- Acute Haemolytic Reaction - due to the transfusion of ABO-incompatible blood.

- Non-Haemolytic Febrile Transfusion Reaction (NHFT) – this occurs in about 1-2% of recipients and usually involves fever and chills, but while it may cause discomfort it is not life-threatening.
- Allergic Reactions – mild allergic reactions may involve a rash, urticaria (hives) and dyspnoea (difficulty breathing), whereas anaphylactic reactions are potentially fatal.
- Transfusion Related Acute Lung Injury (TRALI) – is a significant transfusion-related event, which involves acute respiratory distress and pulmonary oedema. It is one of the most common causes of fatal transfusion reactions.
- Transfusion Associated Circulatory Overload (TACO) – this is characterised by respiratory distress, tachycardia and increased blood pressure.
- Transfusion-Associated Graft Versus Host Disease (TA-GVHD) – this reaction is caused by the proliferation of donor T-lymphocytes, which then destroy the recipient's cells carrying HLA antigens. TA-GVHD is a rare complication but it is usually fatal.
- Post-Transfusion Purpura (PTP) – this is a rare but potentially fatal reaction characterised by the sudden onset of severe thrombocytopenia (an abnormally low amount of platelets) and is often associated with haemorrhage.

The various safety and quality control measures employed by blood establishments such as the IBTS have greatly improved the overall safety of the transfusion process. However, where adverse transfusion-related events occur, most of those reported relate to mistransfusion and the non-infectious risks of transfusion.¹⁰ Indeed, the likelihood of receiving an incorrect blood component during a transfusion is generally considered much greater than receiving a transfusion-transmitted infection.¹¹

Given the potential, albeit in most cases rare, risks associated with transfusion, it has been argued that such interventions should only be provided when clinically necessary,¹² and if there are no alternative treatment options available.¹³ The National Haemovigilance Office in Ireland has stated that avoiding unnecessary transfusion remains the prime safety measure.¹⁴ Therefore, when deciding whether or not to provide a transfusion, the risk of not receiving the transfusion should outweigh the potential risk of the recipient suffering a serious reaction to the transfusion.

Consent and Blood Transfusions

Informed Consent and Disclosure of Information

The concept of informed consent is interconnected with the principles of autonomy and bodily integrity. Notwithstanding emergency situations, a medical intervention cannot be provided without the patient's informed consent.^b As such, informed consent is considered an essential prerequisite to the commencement of any healthcare intervention. However, consent must be considered valid, i.e. the individual should have the requisite capacity to make the decision; his/her choice should be voluntary; s/he should be provided with appropriate information, in a format s/he can understand, regarding the benefits, risks, consequences and alternatives to the proposed treatment; and his/her decision should be accurately documented.¹⁵

However, there has been considerable debate within the field of transfusion medicine internationally about whether separate informed consent should be obtained from patients for blood transfusions.¹⁶ For example, in the US there has long been support, particularly through the American Association of Blood Banks (AABB), for specific consent for transfusion.^{17,18} In some US states requirements for written informed consent are recognised in legislation, whereas others rely on common law principles applied through the courts. It is generally agreed that the minimum elements to be discussed with a patient before consenting to a transfusion should include:^{17,18}

- Clarification of the reason for the transfusion, i.e. the purpose and anticipated benefit of the transfusion, including the consequences of not having the transfusion.
- The alternatives to transfusion, which may include the possibility of an autologous transfusion.
- Clarification of the risks associated with transfusion.
- Patients should also be given the opportunity to ask questions and should be informed of their right to refuse a transfusion.

With specific reference to the risks of transfusion, the greater focus on patient autonomy within the healthcare setting has seen a shift in the standard expected towards the disclosure of risks that are considered to be material to a reasonable patient.¹⁸ Several commentators have suggested that patients should be informed

^b In many jurisdictions, proxy decision-makers (e.g. enduring powers of attorney) are legally entitled to make healthcare decisions on behalf of individuals who lack decision-making capacity.

of both those risks that are frequent but relatively mild (e.g. fever, chills and urticaria) as well as those that are rare but could cause serious morbidity or mortality (e.g. haemolytic transfusion reaction or the transmission of HIV or hepatitis).¹⁷

In both Ireland and the UK, the courts have recognised the “reasonable patient” test as the appropriate standard for the disclosure of material risks regarding a medical intervention as part of the informed consent process.^c These developments reflect the greater recognition of patient autonomy and participation in the decision-making process within the healthcare setting. For instance, the recent General Medical Council (GMC) guidelines on consent from the UK highlight the need for healthcare professionals (HCPs) to work in partnership with their patients to ensure good quality care.¹⁹ Similarly, the Irish Medical Council’s *Guide to Professional Conduct and Ethics for Registered Medical Practitioners*, refers to the informed consent process as a means of ensuring respect for “the patient’s autonomy and their right to control their own life”.²⁰

Specific Consent for Blood Transfusion

Although the importance of the informed consent process is well recognised across the healthcare sector in general, concerns have been raised internationally regarding the way in which the consent process for blood transfusion is conducted. Studies have indicated that patients are often not provided with sufficient information to enable them to make an informed choice about undergoing a transfusion. For example, patients are often not adequately informed of the risks, benefits and alternatives to transfusion.^{5,21} In addition, patients may not have been made aware of the need for them to have a transfusion or that they have undergone a transfusion.²¹ Moreover, HCPs often do not document whether or not consent discussions have taken place with the patient.²²

Audits presented to the UK’s Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) “have identified that the practice of obtaining any form of valid consent for blood transfusion is highly variable in the UK”.²³ For example, some hospitals insisted on full informed and written consent, whereas for others there was little evidence of patients being provided with information in advance of transfusions.²⁴ SaBTO found that patients were not always given information on

^c For example see *Geoghegan v Harris* [2000] 3 IR 536 and *Fitzpatrick v White* [2008] 3 IR 551.

the risks, benefits and alternatives to transfusion or the right to refuse transfusion. Moreover, often patients were not always made aware that they had received a transfusion, which could lead to patients subsequently donating blood when they should not. SaBTO subsequently conducted a public consultation in 2010 to consult widely on the options for undertaking consent for blood transfusion as well as the potential operational challenges if documented consent were to be mandated.²³ As such, this consultation had three key objectives: identify the preferred option for recording consent; explore the potential operational impact of implementing a standardised form of consent for transfusion; and confirm what type of information patients should receive.

As a result of this consultation SaBTO made 14 recommendations for consent for blood transfusion, which have been endorsed and guidance on their implementation has been distributed within the National Health Service (NHS). SaBTO stated that the GMC's generic standard for consent did not need to be "re-invented" for blood transfusion. Nonetheless, SaBTO recommended that valid informed consent for blood transfusion should be obtained and documented in the patient's clinical record by a HCP. As part of this consent process SaBTO recommended that "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". As part of the governance and oversight of blood transfusion SaBTO recommended that the consent standard developed by Health Improvement Scotland^d should be adopted throughout the UK for consent for blood transfusion. Amongst other criteria, this standard requires that patients' records contain evidence that the reason for the transfusion was explained and discussed with the patient, including the available alternatives to transfusion and the option to refuse.²⁵ This standard also requires that information leaflets explaining the risks, benefits and alternatives to transfusion are readily available for patients. Other issues covered under SaBTO's own recommendations included developments pertaining to: patient information (i.e. the development of a standardised information source for patients; the retrospective provision of information to patients who were transfused but who could not give valid consent at that time); patient and public education (i.e. developing an ongoing programme for educating both patients and the general public about blood transfusion); and professional education (i.e. supporting HCPs to improve their knowledge of consent as well as its relevance and importance in blood transfusion).

^d Health Improvement Scotland was formerly known as NHS Quality Improvement Scotland.

Elsewhere in Europe the EU's Optimal Blood Use project has produced a manual as a resource to help improve the quality of the clinical transfusion process.²⁶ This manual states that hospitals should have standard operating procedures for the provision of information to and documenting consent from patients. In addition, the manual states that, as part of an effective quality system, patients must be informed in good time about their transfusion (i.e. the reasons for it, the benefits and risks involved). Moreover, each patient's clinical notes should record that this information was provided to him or her.

In Australia the National Safety and Quality Health Service Standards provide "a nationally consistent and uniform set of measures of safety and quality for application across a wide variety of health care services", which includes the use of blood and blood products.²⁷ These standards require that:

- Patients are informed about benefits, risks and alternatives of blood transfusion in a format they can understand.
- Care plans are developed in partnership with patients and carers.
- Informed consent is undertaken and documented for all blood transfusions in accordance with the informed consent policy of the health service organisation.

Therefore, while it is necessary for specific informed consent to be obtained for blood transfusions, the exact mechanism involved may vary. For example, the 2011 edition of the *Guidelines for the Administration of Blood Products* state that consent for transfusion must be documented in the patient's medical record either on a generic or transfusion-specific consent form or in the progress notes.²⁸ The variability in how informed consent for transfusion is documented is also evident between different states and territories within Australia. For instance, Queensland requires patients to complete a specific transfusion consent form,^e in the Australian Capital Territory consent must be documented in the patient's healthcare record,²⁹ and in Victoria consent for transfusion must be documented either in a consent form or in the healthcare record.³⁰

In Canada, while obtaining specific consent for blood transfusion has been recommended at a national level, the mechanisms involved can vary both regionally and locally. In 1997 an expert working group of the Canadian Medical Association recommended that "when feasible, the patient's consent to a

^e For more information see the website: http://www.health.qld.gov.au/consent/documents/shared_file_03.pdf, accessed on 25 April 2012.

transfusion of red blood cells, plasma or both should be obtained and recorded in the patient's medical chart.³¹ More recently, the Canadian Standards Association (CSA) has stated that operating procedures should be in place for obtaining informed consent for blood transfusion and outlines some of the information that should be provided to potential transfusion recipients as part of this process.³² However, the CSA do not specify how the consent process should be documented. As in Australia, different requirements for the documentation of consent apply in different areas of Canada, for example in Alberta a generic or transfusion-specific consent form must be completed,³³ in Newfoundland and Labrador consent must be documented in the patient's medical record,^f whereas in Manitoba consent may be documented in the patient's medical record and/or in a consent form.³⁴

Consent for Blood Transfusion – The Situation in Ireland

Similarly to the situation outlined by SaBTO in the UK, the practice of obtaining consent for blood transfusion varies within Ireland. The HSE states on its website that if a patient is going to receive a blood transfusion as part of his/her planned treatment then the doctor in charge of his/her care will usually obtain that individual's informed consent for the procedure.³⁵ A number of regional HSE guidelines also state that if a transfusion is required as part of a patient's medical treatment then his/her verbal consent must first be obtained,^{36,37} which in some instances is required to be documented in the medical notes.³⁸ In addition, a limited number of hospitals require a patient's written informed consent for a blood transfusion. Moreover, although the HSE states on its website that obtaining consent for a blood transfusion is not a legal requirement it also recognises that most HCPs consider obtaining consent for such procedures to be best practice.³⁵ Despite this it has been suggested that in Ireland it is not common practice for HCPs to seek specific informed consent for the transfusion of blood components as such interventions are considered to be part of a patient's overall treatment and care. Therefore, consent for the transfusion is generally implied through that patient's consent to medical treatment.¹ An exception to this approach would usually apply in the case of patients who are members of the Jehovah's Witness faith and, therefore, may refuse a blood transfusion or certain blood products for religious reasons.

^f For more information see the website:
http://www.health.gov.nl.ca/health/bloodservices/pdf/physician_information.pdf, accessed on 28 August 2012.

There is greater consistency with regard to the importance of providing written information to patients in relation to blood transfusions and transfusion-specific patient information leaflets appear to be available in all Irish hospitals. In general these information leaflets provide an overview about blood transfusions, which may include:

- What a blood transfusion is and what it entails;
- The purpose of and the benefits associated with a blood transfusion;
- The risks associated with blood transfusions;
- The measures taken to ensure that blood is safe, uncontaminated and correctly matched;
- The reactions that may be experienced while undergoing a transfusion and the associated treatments;
- An outline of the alternatives to a blood transfusion.

In addition, patient information leaflets generally provide a reminder to the patient that any additional concerns or questions s/he might have can be discussed with a doctor or nurse.

Is Specific Informed Consent for Transfusion Necessary in Ireland?

Having considered developments in best practice internationally, the question arises about the best approach to take in obtaining consent for blood transfusion in Ireland. There are three different models of consent that could be applied in the Irish healthcare setting in relation to blood transfusion:

1. Implied Consent with Additional Information
2. Specific Informed Consent
3. Specific *and* Separate Informed Consent

1. Implied Consent with Additional Information

With this model specific informed consent for blood transfusion is not deemed necessary as the transfusion would be considered as part of the patient's overall care and treatment. Accordingly, should the need for a transfusion arise during the course of an individual's treatment, his/her consent would be implied. As part of this model if a patient was considered likely to require a blood transfusion, s/he would be provided with information (e.g. in the form of a patient leaflet) about blood transfusions as well as having the opportunity to ask his/her doctor additional questions or raise particular concerns. As noted above, this appears to

be the predominant approach currently adopted in Ireland in relation to consent for blood transfusion.

Whether or not such implied consent is considered sufficient and appropriate is the subject of some debate. Blood transfusion is not a completely risk free procedure, therefore, in order to exercise his/her autonomy in deciding whether or not to receive a transfusion an individual should be fully informed of the benefits, risks and likely consequences involved as well as any alternative treatments available. Patient information leaflets often provide much of this information and research has indicated that such written information is considered helpful by patients.^{21,39} However, these information leaflets tend to outline issues in a general sense and may not, necessarily, encompass all the specific aspects of an individual's case. Moreover, while these patient information leaflets generally emphasise that transfusions are only provided when they are necessary, in many cases, particularly in Ireland, they do not explicitly state that an individual has the right to refuse a blood transfusion. Therefore, in order to be fully informed of all the options available, some level of discussion would usually still be required between the patient and his/her HCP. In essence, such patient information leaflets should be seen as supplemental to pre-transfusion consent discussions and not as a replacement for such discussions.⁴⁰ Indeed, the EU's Optimal Blood Use Project has stated that clinicians have a professional duty to inform patients and ensure that they know if and why a transfusion is required.²⁶

While facilitating autonomous decision-making through such "two-way" communication between HCPs and their patients is important, the accurate documentation of the patient's decision is also considered to be a necessary component of valid informed consent. However, the extent to which patients' decisions regarding transfusion are currently documented varies both within and between different countries. For example, evidence from a number of jurisdictions have highlighted some problems regarding the documentation of consent for transfusion.^{22,39,41} Such a lack of documentation in this regard undermines the informed consent process and could, therefore, negatively impact on an individual's autonomy.

In light of the issues outlined with existing transfusion consent practices, implementing a system of specific informed consent may be more appropriate.

2. Specific Informed Consent

A second option that could be adopted is a model whereby specific consent for blood transfusion is obtained as part of the overall consent process and documented in a patient's healthcare record (as suggested by SaBTO in the UK).

HCPs and clinicians in particular have a duty of care towards their patients, which includes a professional duty to inform them about their treatment options (i.e. the benefits, risks, alternatives and potential outcomes). This requires ongoing discussion with patients to inform them, help alleviate their concerns and answer their questions. Accordingly, such in-depth HCP-patient discussions are a necessary component of the informed consent process. As part of this process the reasonable patient standard dictates that the material risks associated with an individual's treatment, of which blood transfusion may be a part, should be disclosed.

Nonetheless, where blood transfusion is a potential consequence of another medical intervention (e.g. surgery) it is important that the benefits and risks of transfusion are considered within the overall context of the benefits and risks associated with this other intervention as well. That is, the emphasis placed on the risks associated with blood transfusion during a consent discussion should reflect their relative magnitude in the whole treatment process.⁴⁰

A number of commentators have argued that the introduction of specific informed consent for blood transfusion is a long-awaited and vital step towards patient autonomy.^{16,21} By obtaining and documenting a patient's specific consent for transfusion, his/her medical record would thus contain evidence of the informed consent process, namely: that information was provided to the patient; the reason for the transfusion, the attendant benefits and risks, as well as any alternative treatments and the right to refuse the transfusion were explained and discussed; and that the individual understood the information provided before making his/her final decision. Previously in Ireland, the National Blood Users Group in its 2004 *Guidelines for the Administration of Blood and Blood Components* recommended that the risks, benefits and alternatives to transfusion should be discussed with the patient and recorded in his/her medical records.⁴² However, in an emergency situation it is unlikely that such pre-transfusion discussion could take place, for example, because the patient may lack capacity to be involved in such a discussion and/or the urgent necessity to provide a blood transfusion. It is important from a safety point of view that such individuals are

subsequently informed that they have received a blood transfusion. Notwithstanding emergency situations, a patient may not have sufficient capacity to make a decision regarding his/her treatment, which may include a blood transfusion. In such instances, this decision should be made by the treating HCP in the patient's best interests and should take account of the patient's known values and preferences regarding the treatment.⁹

Given that blood transfusion is predominantly considered to be safe, some commentators have questioned whether specific consent for transfusion is actually necessary. For example, Hunt et al. do not believe that mandating consent or practical competency testing for HCPs involved in blood transfusion are solutions in making blood transfusion any safer and, therefore, query whether healthcare resources utilised for these purposes could be better deployed elsewhere.⁴¹

In addition, it could be argued that if prior informed consent for blood transfusion is considered necessary then such prior consent should also be required for all other potential interventions that might be required during a medical or surgical procedure (e.g. anaesthesia, x-rays, haematology etc.). In addition, requiring specific informed consent for transfusion could raise a number of resource allocation issues particularly in relation to the availability of HCPs to conduct the consent process.

However, implementing a requirement to obtain and document specific consent for blood transfusions could assist in providing greater insight to patients into how decisions relating to transfusion are made and the role and rights of patients in such decisions. Given the somewhat controversial history of blood transfusion both in Ireland and elsewhere (e.g. surrounding the transmission of infectious diseases such as Hepatitis C and HIV),^{1,5,43} such openness and transparency may help to improve the public's trust in, as well as their awareness and perception of blood transfusion practices. There is evidence to suggest that patients' attitudes to blood transfusion vary, particularly in relation to the perception of the safety of these procedures.^{5,44,45} Therefore, as noted by a number of commentators, while the likelihood of receiving the wrong blood or acquiring a blood-borne infection may be small these considerations are still likely to be important to patients.^{16,21} This links back to the reasonable patient standard regarding the disclosure of

⁹ Legislative provisions for supported and substitute decision making for individuals who lack capacity or have limited capacity are proposed to be introduced in the *Assisted Decision-Making (Capacity) Bill*.

risks as part of the informed consent process. Greater patient participation in transfusion decisions, through the consent process may, therefore, help to foster more trust in the transfusion service and improve negative attitudes. Trust has been identified as an important component in the proper functioning of the clinician-patient relationship.⁴⁶

Such trust may be further enhanced by ensuring greater consistency and standardisation of the information provided to patients about blood transfusion. This could potentially be done through specific education and training of HCPs regarding transfusion practices and about obtaining informed consent. In addition, the development of a national blood transfusion patient information leaflet could also help to build trust and raise awareness, through the provision of consistent information to the public and patients about blood transfusion. Both of these approaches have been recommended by SaBTO in the UK.²³

Finally, blood transfusions tend to be provided when they are considered necessary, at which point the risks of not receiving a transfusion may be greater than any potential risks associated with the transfusion itself. While this is usually the case, medically unnecessary transfusions do sometimes occur,^{45,47} as has been documented by the National Haemovigilance Office here in Ireland, where such unnecessary transfusions have occasionally been provided to patients in error.^{11,14}

3. Specific and Separate Informed Consent

Taking the requirement for specific consent for blood transfusion further might entail the adoption of a model whereby patients are provided with information relating to transfusion and are then required to sign a separate transfusion-specific consent form. This approach has been adopted and is legally mandated in many states within the US.¹⁷

It could be argued that this approach helps to clarify that the patient's consent is being obtained specifically for blood transfusion. As noted above, documentation of an individual's consent is a necessity and a completed consent form provides a record of this consent, however, it is equally important to recognise that the form itself does not equate to informed consent.^{22,40} Indeed, it could be argued that obtaining a signed consent form for blood transfusion may have more to do with defensive legal practices rather than emphasising patient autonomy. In this

regard it is important that the consent process does not become diluted to a “form-filling” exercise.

This raises the question of whether the additional burden of requiring patients to complete a separate transfusion-specific consent form is a necessary and proportionate approach to enhancing their autonomy. It has been argued that documenting the discussion and sharing of information about a treatment in the patient’s record contemporaneously can help to validate the informed consent process better than relying on other methods of documentation.⁴⁰ Documenting the discussion and the patient’s consent in his/her record could, therefore, be seen as proportionate by helping to maintain the focus on the informed consent process (and the patient’s autonomy) as opposed to focusing on completing a specific form.

Committee Opinion

The practice of obtaining consent for blood transfusion within the Irish healthcare system varies. For example, a limited number of hospitals require written informed consent, whereas others rely on verbal consent, which may or may not subsequently be documented in the patient’s healthcare records. However, in the majority of cases it is not customary to obtain specific informed consent for blood transfusion in Ireland. Rather transfusions are considered to be part of the overall treatment that is provided to patients and consent is, generally, deemed to be implied. In light of the differences outlined, the Committee is of the opinion that there is a need for greater consistency and transparency in how the consent process for blood transfusion is conducted across the healthcare system. Moreover, previous incidents, both nationally and internationally, surrounding the transmission of HIV and Hepatitis C through blood transfusions have left as a legacy a certain degree of negativity in relation to blood transfusion practices. The Committee takes the view that changes need to be made in the interests of patient autonomy and to help provide greater openness and transparency into, as well as greater patient participation in, the decision-making process relating to blood transfusions, thereby helping to improve public trust in these practices. Given the existing burdens on the healthcare system, the Committee considers that implementing a system of specific informed consent for blood transfusion represents an ethically appropriate and proportionate measure to achieve these objectives.

The Committee would, therefore, prefer that a pre-transfusion dialogue occurred between the HCP and the patient, which involved an explanation of the potential risks and benefits of transfusion, the available alternatives to blood transfusion, the right to refuse transfusion as well as providing both the time and the opportunity for patients to ask questions. Such discussions are the cornerstone of the informed consent process, which underpins an individual's ability to exercise his/her autonomy in relation to his/her medical treatment. Indeed, facilitating and participating in such two-way dialogue to help inform patients is part of a HCP's professional duty. Moreover, documenting the discussion that took place, any questions asked, as well as the patient's decision to consent to or refuse the proposed treatment is an essential component of the informed consent process. The lack of adequate documentation of the discussions and decisions pertaining to blood transfusion undermines the informed consent process and could, therefore, impinge on an individual's autonomy.

The Committee does not propose that separate forms should specifically be used for documenting informed consent for blood transfusion. The rationale for this decision is that requiring separate consent forms could create an administrative burden on the existing healthcare system that would be disproportionate to the risks involved. The implementation of various safety and quality control measures over the years has made blood transfusion practices much safer. Indeed, evidence suggests that the risks posed by transfusion are more likely to be due to mistransfusion errors than to transfusion-transmitted infections. Nonetheless, while certain risks associated with blood transfusion may be more remote, they still represent information that a "reasonable patient" would want to have disclosed to him/her.

However, the Committee takes the view that provided all the pertinent information is communicated to patients in a meaningful and comprehensible manner, it is sufficient for the patients' agreement or refusal to be documented in their medical records rather than in a separate consent form. Documenting the discussion and the patient's specific consent or dissent for transfusion in his/her medical record provides important evidence that the informed consent process was undertaken as well as the context of the discussion. While the completion of a separate consent form would also provide such evidentiary value, the form itself does not encompass the informed consent process, i.e. the informed consent process must be documented, but the documentation is not the process. From the Committee's perspective the focus of the informed consent process should be to

ensure that patients are given adequate information to make their decision. It is, therefore, essential to avoid a situation where dialogue and consent are minimised or even replaced with a form-filling exercise, which is aimed more towards defensive medical practice than on upholding patient autonomy and a HCP's duty to inform his/her patients.

Allied to this process, the Committee believes it would be beneficial to provide professional training to HCPs about how to conduct and accurately summarise consent discussions and record patient decisions. In addition, the Committee takes the view that a public awareness campaign incorporating standardised patient information leaflets, online information and material for display in healthcare settings should also be implemented. The Committee is of the opinion that such an endeavour would help to maximise patients' potential to participate in the consent process and to make informed decisions regarding their healthcare. Standardising specific informed consent practices would result in consistency of procedure across the health service, which would not only bolster patient safety and public trust, but would also strengthen the clinician-patient relationship.

As is the case with other medical treatments, in an emergency situation, it may not be possible to obtain a patient's consent for a blood transfusion because s/he lacks capacity and/or the urgent need for the intervention precludes the normal informed consent process. Therefore, in situations where a blood transfusion is deemed necessary to save the life or preserve the health of the patient this treatment may be administered in the absence of the expressed consent of the patient (provided s/he does not have a valid advance healthcare directive refusing a blood transfusion). The Committee believes that following such emergency interventions the patient should be informed that a blood transfusion was provided and the reasons for the transfusion should be explained and additional written information relating to blood transfusion should be provided to the patient.

In conclusion, following its deliberations and consideration of the ethical and practical issues involved the National Advisory Committee on Bioethics proposes that:

For cases where a patient is considered likely to require a blood transfusion, Ireland should adopt a model whereby specific information relating to blood transfusion is provided to, and discussed with, patients

as part of the overall consent process. Following this discussion the attending healthcare professional should seek the patient's specific consent for blood transfusion. The details of the discussion as well as the patient's specific consent for blood transfusion should be clearly documented in his/her healthcare records.

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