When Blood Is Not an Option: The Case for a Standardized Blood Transfusion Consent Form

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Blood transfusion is the most common invasive procedure performed in the United States.[1] Studies have shown that augmenting the necessary consent discussions with simplified written materials can improve patient recall, comprehension and satisfaction.[2] No standardized resources have been implemented, however. We suggest that a standardized patient information worksheet and a consent form clearly documenting a patient's wishes, particularly those patients for whom blood transfusion is not an option, will help facilitate safe care across the entire health care team, increase anesthesiologist comfort in obtaining consent, and improve patient understanding and satisfaction.

Whether in perioperative management, trauma or obtaining consent, the challenges presented by patients who decline blood are significant. Fortunately, blood conservation methods such as cell salvage, acute normovolemic hemodilution, and newer pharmacotherapies such as prothrombin complex concentrates and recombinant products, have given physicians and patients more treatment options than ever before. Discussing these with patients can at times be difficult for anesthesiologists. Some may feel there is not enough time to discuss a more extensive list of treatments and alternatives, while others may not be familiar with the most up-to-date advances in transfusion medicine.

Patients with whom these discussions take place may choose not to consent for transfusion for a number of reasons, including religious beliefs, fear of contamination and other personal objections. The majority of these patients are Jehovah's Witnesses, a Christian group with nearly 2 million self-identifying members in the U.S.[3] and over 8 million worldwide.[4] While it is well recognized within the medical community that adherents are prohibited from accepting blood transfusion, what may be less well known is that this proscription does not apply to *all* blood components. According to their beliefs, Jehovah's Witnesses make a distinction between what they refer to as "major fractions" (erythrocytes, leukocytes, platelets and plasma) and "minor fractions" (those components resulting from further fractionation, such as coagulation factors concentrates or albumin). "Major fractions" are forbidden, even when there is a potential risk to limb, organ or life. However, the decision to accept "minor fractions," recombinant products or other transfusion strategies is a conscientious decision left to each well-informed patient.[5]

To help address these challenges, improve transfusion education and streamline the consent process, we have constructed a "Standardized Blood Transfusion Consent Form." It is a two-page document written at a sixth- to seventh-grade reading level,[6] making it accessible to a broad population.

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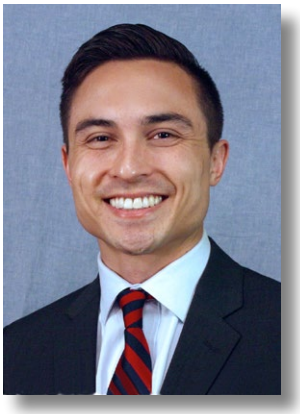

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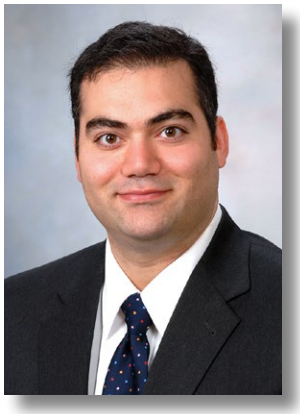

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GENERAL CONSENT FOR BLOOD PRODUCTS – Page 1 of 2

PATIENT NAME: _____ **DATE OF BIRTH:** ____ /____ /_____ **MRN:** _____

Please mark whether you Accept or Decline each of the following:

WHOLE BLOOD COMPONENTS (*some people call these Major Fractions*) Blood carries oxygen and nutrients through the body. The 4 main parts (or components) can be separated and used for treatment.	
RED BLOOD CELLS (Other Names: Erythrocytes, RBCs) take oxygen from your lungs to your organs and tissues. They also take carbon dioxide back to your lungs to breathe out. We give RBCs if your blood count is too low.	☐Accept ☐Decline
WHITE BLOOD CELLS (Other Names: Leukocytes, WBCs) are one of your body's defenses against bacteria, viruses, and diseases the body produces. We give WBCs to help you fight certain diseases.	☐Accept ☐Decline
PLATELETS (Other Name: Thrombocytes) are small pieces of cells. They help your blood make clots that prevent or stop bleeding. We give Platelets if your bleeding is hard to stop or if your Platelet count is very low.	☐Accept ☐Decline
PLASMA is the liquid part of blood. It is made of water, albumin, clotting factors, salts, sugars, fats, vitamins, and hormones. We give this if you need more Plasma or Clotting Factors.	☐Accept ☐Decline
TYPES OF PLASMA ▶ **Frozen (or thawed) plasma (FFP)** is Plasma removed from whole blood. It is frozen so it can be used later. ▶ **Solvent detergent-treated plasma** is Plasma that is cleaned to reduce the chance of infection or allergic reaction.	
FRACTIONATED BLOOD COMPONENTS are separated from whole blood components (*some people call these Minor Fractions*). – – ***Clotting Factors*** *are proteins in Plasma. They help your blood make clots that stop bleeding.* – –	
CRYOSUPERNATANT is plasma that has most of the solid parts taken out. The leftover liquid is called Cryosupernatant. We give Cryosupernatant to replace plasma.	☐Accept ☐Decline
CRYOPRECIPITATE is plasma that has the liquid part taken out. The leftover clotting factors are called Cryoprecipitate. We give Cryoprecipitate to help stop bleeding.	☐Accept ☐Decline
PROTHROMBIN COMPLEX CONCENTRATE is a mix of many clotting factors. We give this mix to help stop bleeding or to reverse the effects of blood thinning medicine.	☐Accept ☐Decline
CONCENTRATED CLOTTING FACTORS are single clotting factors. We give them to help stop bleeding.	☐Accept ☐Decline
ALBUMIN is the main protein in plasma. We give Albumin to increase blood volume.	☐Accept ☐Decline
ANTIBODIES (Other Name: Immune Globulins) are proteins your body makes to fight disease. We can also give you Antibodies to help your body fight some types of infections.	☐Accept ☐Decline
YOUR OWN BLOOD can be used in the procedures below in a closed system. Your blood is not mixed with any other blood.	
APHERESIS (Other Names: Plasma exchange, Plasmapheresis) is when a closed-system machine replaces bad plasma with a good plasma substitute. It is used if your plasma has antibodies that are attacking your body.	☐Accept ☐Decline
AUTO-TRANSFUSION (Other Names: Cell Saver, Cell Salvage, Salvaged Autologous Blood) is when your blood is collected during surgery, washed and filtered, and then given back to you in a closed system.	☐Accept ☐Decline
HEMODILUTION is when your blood is replaced with IV fluids during surgery. After surgery, we give your blood back to you in a closed system.	☐Accept ☐Decline
HEART AND LUNG MACHINE is when your blood flows into a machine that adds oxygen to it. Your blood then flows back into your body in a closed system primed with non-blood fluid. It is used during some surgeries.	☐Accept ☐Decline
DIALYSIS (Other Names: Renal Dialysis, Hemodialysis) is when your blood flows into a machine that filters and cleans it, then flows back into your body in a closed system. It is used if your kidneys are not working well or harmful substances need to be taken out of your blood.	☐Accept ☐Decline
EPIDURAL BLOOD PATCH is when your blood is injected around your spinal cord to stop a spinal fluid leak.	☐Accept ☐Decline
PLATELET GEL is made of your platelets and white blood cells. We use it to cover wounds and help stop bleeding.	☐Accept ☐Decline
RECOMBINANT PRODUCTS are like Whole Blood Components, but they are made with protein technology and do not come from blood.	
RECOMBINANT CLOTTING FACTORS are like the clotting factors that come from Whole Blood Components that are listed above. We give them to help stop bleeding.	☐Accept ☐Decline
RECOMBINANT ERYTHROPOIETIN (Other Names: EPO, ESA, Hematopoietin) is like your body's Erythropoietin. It is a hormone that tells bone marrow to make more red blood cells. We give it if your blood count is too low.	☐Accept ☐Decline
OTHER TREATMENT (Please Specify):	☐Accept ☐Decline

GENERAL CONSENT FOR BLOOD PRODUCTS – Page 2 of 2

PATIENT (this part to be completed by the patient)

Please read the following carefully. Print your name in the blank and then sign below:

I _____ (your name) **WILL ACCEPT** the use of the products check-marked **"Accept"** on Page 1 of this form. I **WILL NOT ACCEPT** the use of the products check-marked **"Decline"** on Page 1 of this form, EVEN IF, in the opinion of my physician, they are necessary to save my life and/or avoid damage to my tissues, organs, or bodily functions.

- I confirm that I have read this form or it was read to me and that I fully understand the information.
- I confirm that I have had the chance to ask questions and that I am satisfied with the answers.
- I understand that my choice to accept or decline the blood products listed above will be enforced until I clearly state otherwise.
- I understand that my choice to accept or decline the blood products listed above will be enforced even if I am unconscious or unable to express my wishes due to medication or illness.
- I understand that my choice to accept or decline the blood products listed above cannot be changed by another person unless I have told the hospital in writing that the person has the authority to make decisions for me.
- I understand that my choice to accept or decline the blood products listed above will be respected by all the doctors who treat me.

Signature: _____ **Date:** _____ **Time:** _____

Witnessed by: _____ **Date:** _____ **Time:** _____

PHYSICIAN (this part to be completed by the physician)

I confirm that I have explained such appropriate options as are available to the patient in terms which in my judgment are suited to the understanding of the person named above. I further confirm that I have emphasized my clinical judgment of the potential risks and benefits to the patient and/or person who nonetheless understood and imposed the limitations expressed above.

I acknowledge that this limited consent will not be overridden unless revoked or modified.

Name of Physician: _____

Signature: _____ **Date:** _____ **Time:** _____

Proposed "Standardized Blood Transfusion Consent Form" for use with adult patients for whom blood is not an option. This template would undergo final revision and approval prior to publication.

The first page is a worksheet detailing the more commonly used blood components and blood conservation modalities. Each item contains a brief description of its function and when it might be used, with an accompanying pair of "accept" and "decline" checkboxes for the patient to indicate preference. Color-coded groupings divide the blood products by origin – whole blood components ("major fractions"), fractionated components ("minor fractions"), recombinant products (synthetic) and closed-system autologous blood treatment modalities (e.g., cell salvage, autologous blood, cardiopulmonary bypass).

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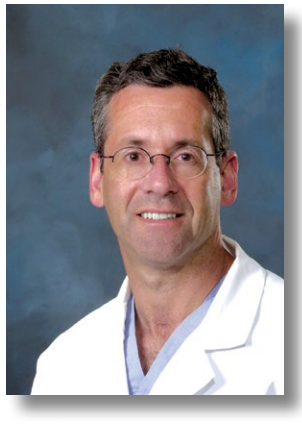

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The patient reads the description of the blood component or treatment modality and then chooses to "accept" or "decline" it. Moving down the list, the blood-derived components become more fractionated and their color lightens. This visually distinguishes each component's origins, augmenting the textual information. The worksheet's structure also benefits anesthesiologists, as the "accept" and "decline" boxes are aligned in a single column, allowing one to quickly scan for any divergence. The worksheet further serves as a general consent checklist for anesthesiologists.

The second page provides signatory confirmation that the patient has discussed the use of blood products and other options with the anesthesiologist and understands the risks, benefits and alternatives. Furthermore, in signing this page, the patient confirms the choices indicated on page one.

"Blood conservation methods, recombinant products and novel alternative therapies have made inspiring progress in meeting the challenges posed by patients for whom blood is not an option."

The two pages can be used in tandem as a consent form. Alternatively, the first page can be utilized independently, serving as an education resource and means of recording the patient's blood transfusion preferences for future use. This ensures that the information is not only delivered but that it is also correct.

It should be noted that this worksheet is intended for use only with adults who are legally competent to provide informed consent, including denial of treatment. In pediatrics, this form would not be appropriate given the medical, ethical and legal complexities surrounding this issue.[7] A standardized blood transfusion consent form can still be valuable in these situations, though, by serving as an educational tool and aid to discussions about alternative therapies with parents or legal guardians.

Blood conservation methods, recombinant products and novel alternative therapies have made inspiring progress in meeting the challenges posed by patients for whom blood is not an option. The use of a standardized blood transfusion consent form, available to anyone and modifiable as needed, would help further this progress by improving communication and efficiency. Just as important, by supporting patient understanding and participation, the form would instill a sense of empowerment for patients, improve patient-anesthesiologist communication and trust, and increase patient satisfaction.

As the Agency for Healthcare Research and Quality (AHRQ) notes, "... studies have shown that improved communication between practitioners and patients leads to improved patient outcomes, less [sic] medical errors, and lower rates of malpractice claims. Adequacy of the informed consent process has been more firmly linked to patient satisfaction."[2] Whether used as a consent form, an educational tool or both, we are optimistic that the "Standardized Blood Transfusion Consent Form" will help meet an under-recognized need and be a valuable resource for anesthesiologists and the entire health care team.

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