

PAUL GANN BLOOD SAFETY ACT

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BLOOD CENTERS OF CALIFORNIA BOARD MEETING

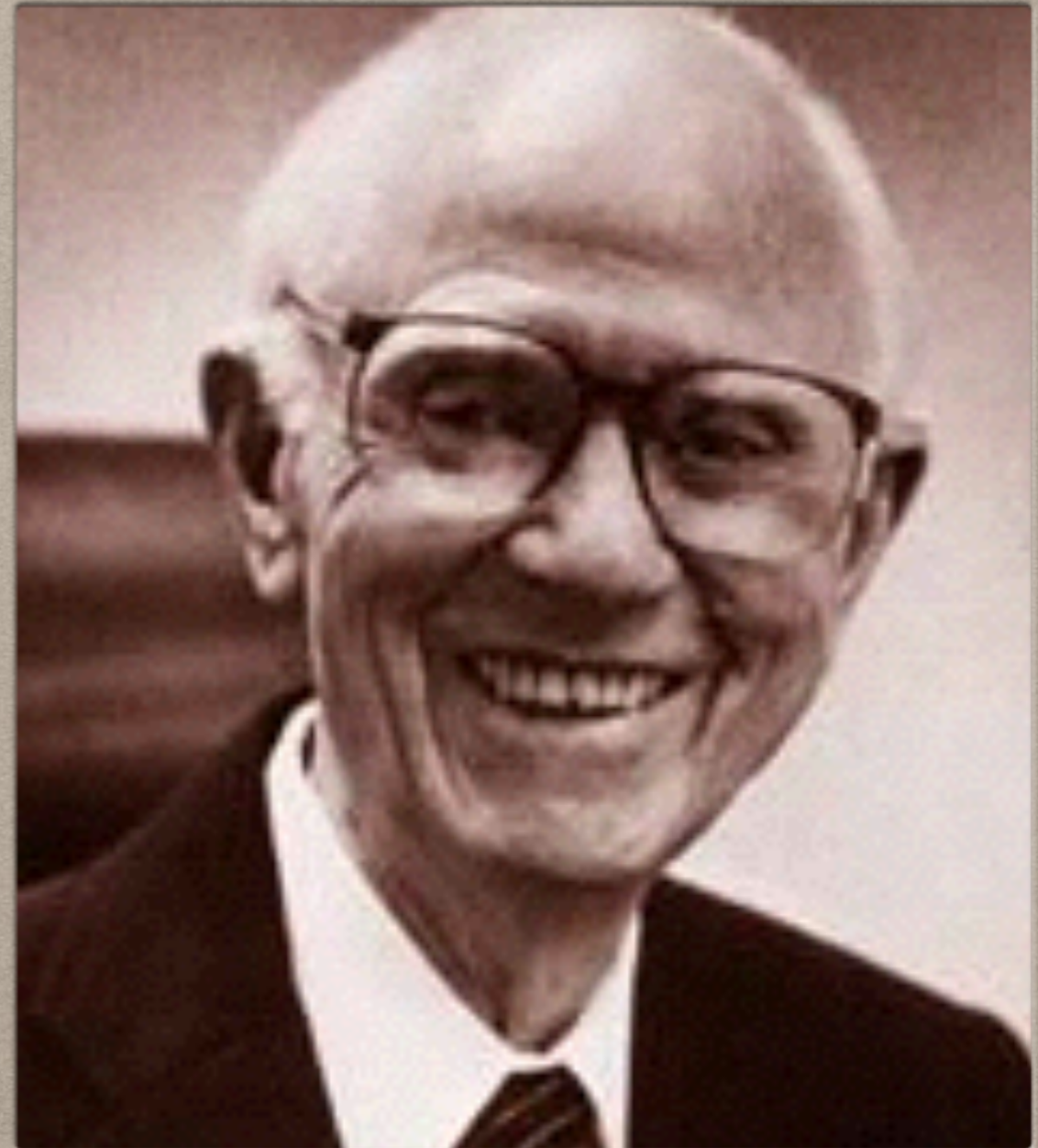
HISTORY

- 1987:
President Reagan donated a unit of autologous blood prior to prostate surgery
- He recommended autologous donation on his radio broadcasts
- His unit was frozen and stored for three years at Bethesda Naval Hospital



HISTORY

- Paul Gann was a conservative California lawmaker who contracted HIV/AIDS through a blood transfusion in 1987
- Paul Gann Blood Safety Act became law in 1990
- Mandates that a physician discusses risks and benefits of blood transfusion with potential recipients



PAUL GANN BLOOD SAFETY ACT

- Health and Safety Code Section 1645(a-g)
- 1645(a) Whenever there is a reasonable possibility, as determined by a physician and surgeon or doctor of podiatric medicine, that a blood transfusion may be necessary as a result of a medical or surgical procedure, the physician and surgeon or doctor of podiatric medicine, by means of a standardized written summary as most recently developed or revised by the State Department of Public Health pursuant to subdivision (e), shall inform, either directly or through a nurse practitioner, certified nurse midwife, or a physician assistant, who is licensed in the state and authorized to order a blood transfusion, the patient of the positive and negative aspects of receiving autologous blood and directed and nondirected homologous blood from volunteers. For purposes of this section, the term "autologous blood" includes, but is not limited to, predonation, intraoperative autologous transfusion, plasmapheresis, and hemodilution.

PAUL GANN BLOOD SAFETY ACT

- PARAPHRASED BELOW
- 1645(a) Whenever ... a blood transfusion may be necessary, the *doctor*, by means of a standardized written summary as most recently developed or revised by the State Department of Public Health pursuant to subdivision (e), shall inform, either directly or through *another health professional*, the patient of the positive and negative aspects of receiving autologous blood and directed donation and blood from volunteer donors
- For purposes of this section, the term "autologous blood" includes, but is not limited to, predonation, intraoperative autologous transfusion, plasmapheresis, and hemodilution.
 - Predonation - donate for self days to weeks before surgery
 - intraoperative - donate for oneself early in surgery to give back at end of surgery
 - plasmapheresis - unsure of intent
 - hemodilution - essentially same as intraoperative

PAUL GANN BLOOD SAFETY ACT

- 1645(b) The person who provided the patient with the standardized written summary pursuant to subdivision (a) shall note on the patient's medical record that the standardized written summary was given to the patient.
- PARAPHRASED
- 1645(b) Healthcare professional **MUST DOCUMENT** in patient's medical record that Paul Gann Blood Safety Act written document was given to the patient.

PAUL GANN BLOOD SAFETY ACT

- 1645(c) Subdivisions (a) and (b) shall not apply when medical contraindications or a life-threatening emergency exists.
- PARAPHRASED
- 1645(c) Documentation not required in case of emergency

PAUL GANN BLOOD SAFETY ACT

- 1645(d) When there is no life-threatening emergency and there are no medical contraindications, the physician and surgeon or doctor of podiatric medicine shall allow adequate time prior to the procedure for predonation to occur. Notwithstanding this chapter, if a patient waives allowing adequate time prior to the procedure for pre donation to occur, a physician and surgeon or doctor of podiatric medicine shall not incur any liability for his or her failure to allow adequate time prior to the procedure for predonation to occur.

PAUL GANN BLOOD SAFETY ACT

- PARAPHRASED 1645(d) For planned elective surgeries that may involve transfusion, the healthcare professional shall allow adequate time prior to the procedure for predonation to occur. If a patient waives allowing adequate time prior to the procedure for pre donation to occur, the healthcare professional shall not be liable.

PAUL GANN BLOOD SAFETY ACT

- 1645(e) The State Department of Public Health shall develop and annually review, and if necessary revise, a standardized written summary which explains the advantages, disadvantages, risks, and descriptions of autologous blood, and directed and nondirected homologous blood from volunteer donors. These blood options shall include, but not be limited to, the blood options described in subdivision (a). The summary shall be written so as to be easily understood by a layperson.

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- PARAPHRASED 1645(e) The State Department of Public Health shall develop and annually review, and if necessary revise, a written document which explains the advantages, disadvantages, risks, and descriptions of autologous blood, directed and volunteer donated blood. The summary shall be written so as to be easily understood by a layperson.

PAUL GANN BLOOD SAFETY ACT

- 1645 (f) The Medical Board of California shall publish the standardized written summary prepared pursuant to subdivision (e) by the State Department of Public Health and shall distribute copies thereof, upon request, to physicians and surgeons and doctors of podiatric medicine. The Medical Board of California shall make the summary available for a fee not exceeding in the aggregate the actual costs to the State Department of Public Health and the Medical Board of California for developing, updating, publishing and distributing the summary. Physicians and surgeons and doctors of podiatric medicine shall purchase the written summary from the Medical Board of California for, or purchase or otherwise receive the written summary from the Web site of the board or any other entity for, distribution to their patients as specified in subdivision (a). Clinics, health facilities, and blood collection centers may purchase the summary if they desire.

PAUL GANN BLOOD SAFETY ACT

- PARAPHRASED 1645 (f) The Medical Board of California shall publish the standardized written summary prepared by the State Department of Public Health and shall distribute copies thereof, upon request, to healthcare professionals. The Medical Board of California shall not charge more than the actual costs to the State Department of Public Health and the Medical Board of California for developing, updating, publishing and distributing the summary. Healthcare professionals shall purchase the written summary from the Medical Board of California or may download the summary from the Web site of the board or any other entity for, distribution to their patients as specified in subdivision (a). Clinics, health facilities, and blood collection centers may purchase the summary if they desire.

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- 1645 (g) Any entity may reproduce the written summary prepared pursuant to subdivision (e) by the State Department of Public Health and distribute the written summary to physicians and surgeons and doctors of podiatric medicine.

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- PARAPHRASED 1645 (g) Any healthcare organization may reproduce the written summary and distribute it to healthcare professionals.
- Many hospitals have incorporated the information into consent forms

2011

THE 2011 NATIONAL BLOOD COLLECTION AND UTILIZATION SURVEY REPORT

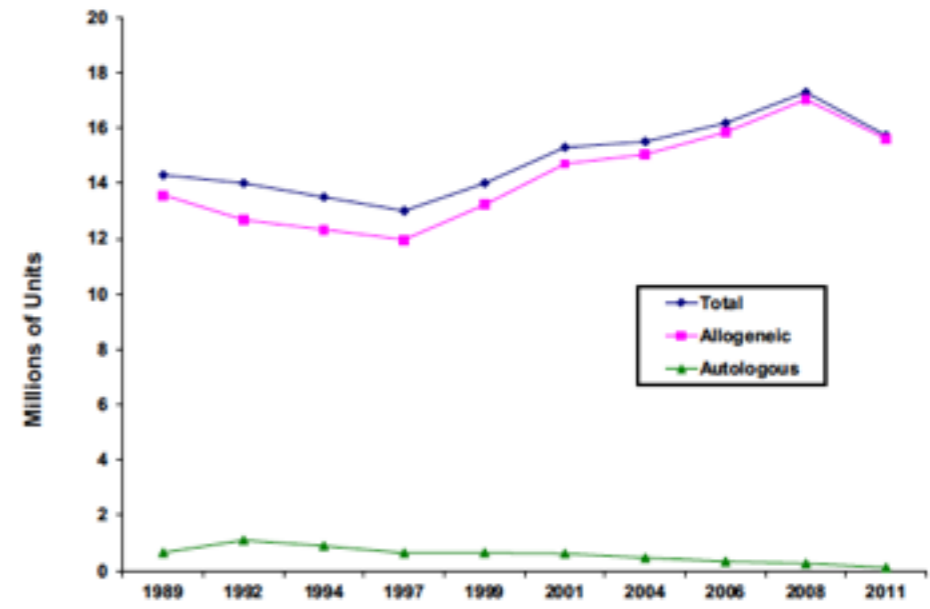


Figure 3-1. Allogeneic, autologous, and total whole blood and red cell collections, 1989-2011.

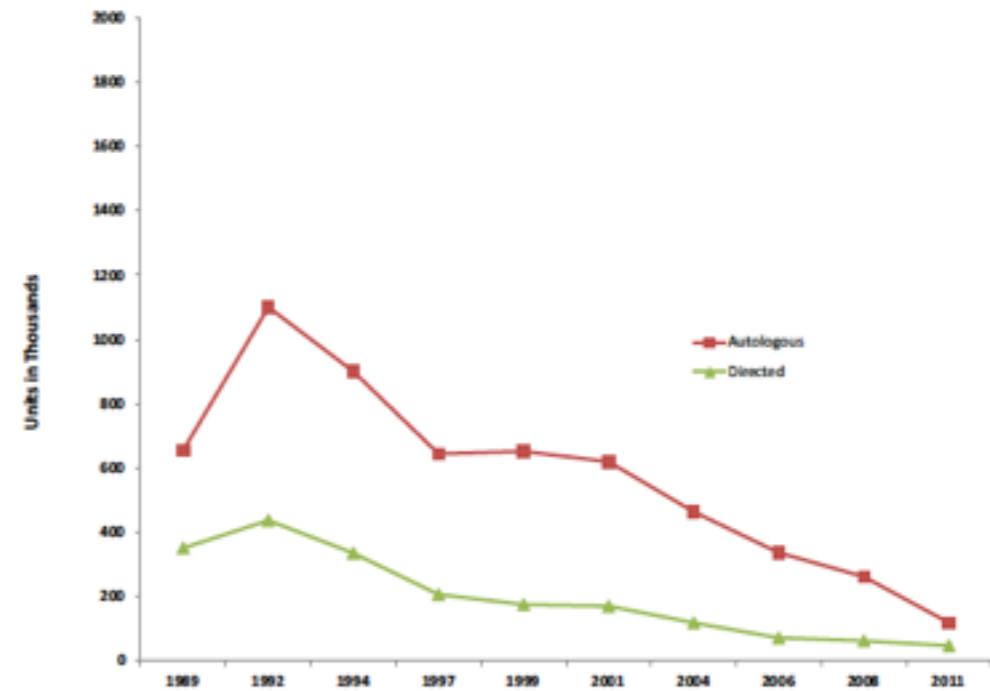


Figure 3-2. Autologous and directed whole blood and red cell collections, 1989-2011.

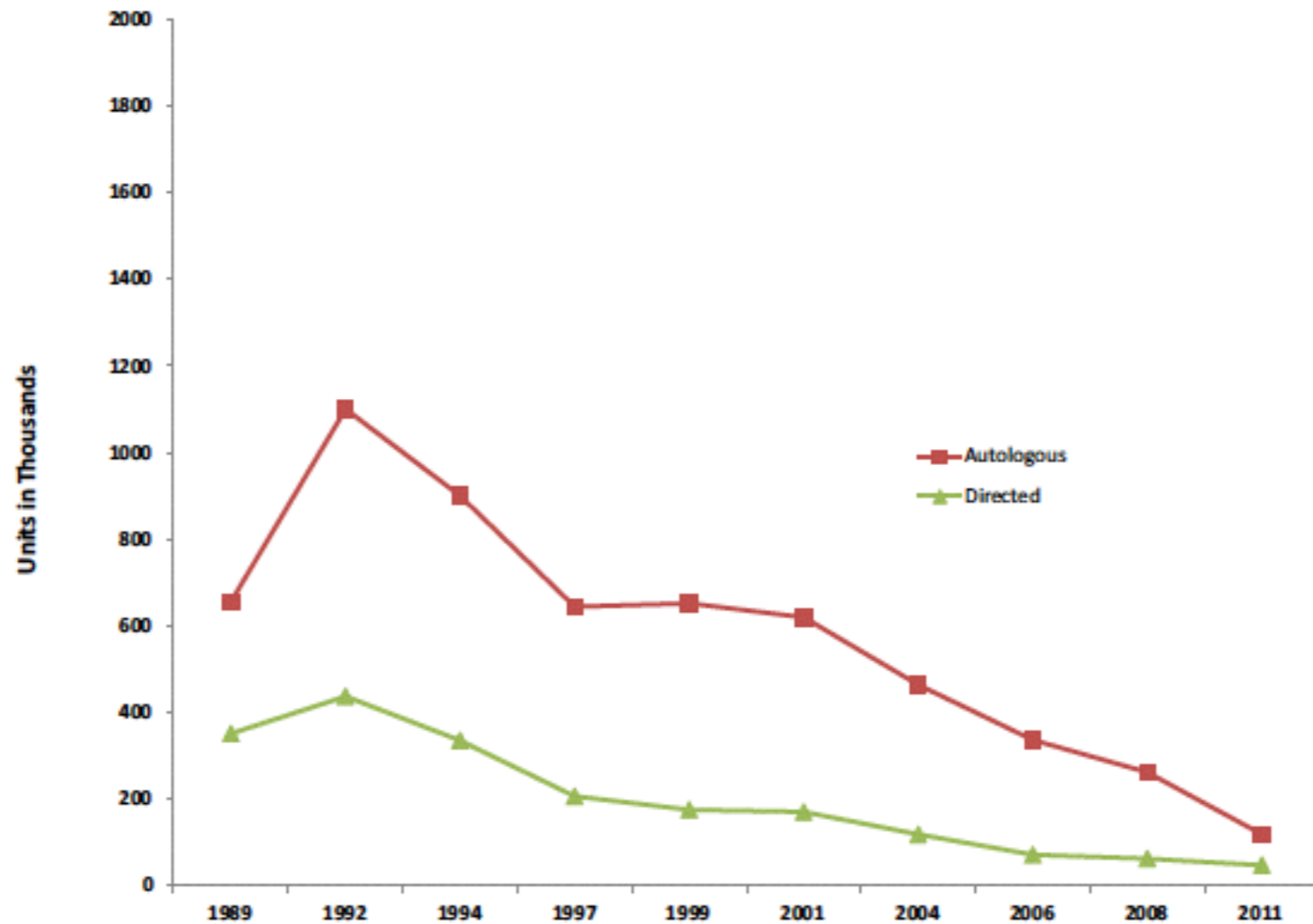


Figure 3-2. Autologous and directed whole blood and red cell collections, 1989-2011.

Autologous Blood Utilization

1992: >1.1 million collections

2008: 253,000 collections

2011: 117,000 collections (nearly half were not transfused)

ACTION ITEMS

- Revision of Patient's Guide to Blood Transfusion is necessary
 - update current risks of transfusion
 - decreased role of preautologous blood donation
 - change format from trifold?
- Propose Paul Gann Blood Safety Act summary can be used as informed consent with signatures
- Revision of Paul Gann Blood Safety Act?
 - eliminate requirement for preautologous blood donation notification vs. use of document for informed consent purposes
 - removal of section d?

current trifold

If you have additional questions about your options for blood transfusion, please ask your doctor. Information also can be obtained by calling your local community blood center or hospital blood bank.

References:

1. Stramer SL, Glynn SA, Kleinman SH et al. "Detection of HIV-1 and HCV infections among antibody-negative blood donors by nucleic acid-amplification testing." New England Journal Medicine vol 351, pp.760-768, August 2004.

* The risk estimates were adjusted to include first time and repeat blood donors.

2. U.S. Department of Transportation's Fatality Analysis Reporting System website 2003 data:

http://www.hwysafety.org/research/fatality_facts/general.html.

This brochure is provided as a source of information and is not to be considered a replacement for the **Informed Consent** process prior to the transfusion of blood.

This brochure was developed by the
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Laboratory Field Services
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In partnership with the
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(Revised 6/06)

A Patient's Guide to Blood Transfusion



**California Department of
Health Services**

June 2006

If you need blood, you have several options. These options include receiving blood from the community, using your own blood (autologous), or blood from donors that you have selected (designated donors). Your options may be limited by time and health factors. Although you have the right to refuse a blood transfusion, this decision may hold life-threatening consequences.

It is important to weigh the risks, costs and benefits of donating your own blood before surgery. Many elective surgeries do not require blood transfusions. If you have questions about transfusion needs or options, please ask your doctor. Check with your insurance company about your costs for donation. If you choose not to donate your own blood, or if more blood is required than expected, you may receive blood other than your own.

Community Donors. Hospitals maintain a supply of blood from volunteer (unpaid) community donors to meet transfusion needs. Community blood donors are screened by a thorough medical history, and then tested with the most accurate technology available.

Our nation's blood supply is very safe and high in quality. Nothing in life is risk free; however, the risks associated with blood transfusions are very small. The chance that a unit (pint) of blood will transmit

Human Immunodeficiency Virus (HIV) (the virus that causes Acquired Immunodeficiency Syndrome (AIDS)) or hepatitis C is about 1 in 2 million. The chance that a unit (pint) will transmit hepatitis B is less than 1 in 200,000.¹ Although the risk for other serious infections exist, that risk is much less than the annual risk of dying in a motor vehicle accident in the United States (1 in 7,000).²

Using your own blood – Autologous Donation. Using your own blood (autologous) can minimize the need for transfusion with donor blood. Using your own blood will reduce, but not eliminate, the risk of transfusion-related infections and allergic reactions.

Patients who donate their own blood before surgery have lower blood levels at the time of surgery and, therefore, have a greater chance of needing transfusions during or after their surgeries. Autologous blood donations are not an option for all patients. It may not be safe for you to donate. Ask your doctor if autologous donation is appropriate for you.

Donating BEFORE Surgery. Blood banks can draw your blood and store it for your use. This process usually is performed for a planned surgery. Blood can be stored for only a limited period of time, so coordinating the donations with the date of surgery is important.

Donating DURING Surgery and/or After Surgery. Immediately before surgery, your doctor may be able to remove some of your blood and replace it with other fluids. After surgery, the blood that was removed may be returned to you.

In addition, the surgeon may be able to recycle your blood during surgery. Blood that normally is shed and discarded during surgery could be collected, processed, and returned to you. A large volume of your blood can be recycled in this way.

Blood that is lost after surgery may be collected, filtered, and returned to you.

Designated Donors. Although the blood supply today is very safe, some patients prefer to receive blood from people they know – “designated (or directed) donors.” This blood is not safer than blood from volunteer community donors. In some cases it may be less safe because donors known to the patient may not be truthful about their personal history. Blood donated by someone who was recently exposed to HIV or other infections could pass the screening tests, and infect you.

Designated donors must meet the same requirements as community donors. Several days notice is required for the additional processing of designated donors.

proposed trifold

This document provides written information regarding the benefits, risks, and alternatives of transfusion of blood or primary components of blood (including, without limitation red blood cells, plasma, platelets, or others collected from the patient (autologous) or another person (allogeneic). This material serves as a supplement to the discussion you have with your physician. It is important that you fully understand this information, so please read this document thoroughly. If you have any questions regarding the procedure, ask your physician prior to consenting to receive a transfusion.

Information about the Treatment

Reason for treatment (diagnosis, condition, or indication)

Transfusions of blood or blood products (components of blood including red blood cells, plasma, platelets, or others) are provided to increase the amount of these blood products in your blood stream when they are below a reasonable level for your health.

Brief description of the treatment

Transfusions are given by vein (usually a vein in the arm) using a new sterile disposable needle. The transfusion may be made up of red blood cells, plasma, platelets or other specialized products made from blood. Your doctor will decide on the right amount and type of blood product based on your medical condition

or diagnosis.

Potential benefits of the treatment

Transfusion of blood or blood products may be necessary to correct low levels of blood components in your body, and may also make you feel better. In some cases, failure to receive blood transfusion(s) may result in death.

Risks and side effects of the treatment

Known risks of this treatment include, but are not limited to:

Infection or irritation where the needle is placed.

Temporary reaction such as a fever, chills, or skin rashes.

Other rare but more serious complications may occur such as allergic reactions, heart failure due to fluid overload, acute pulmonary edema (fluid leaking into the lungs), shock, or death.

Transfusions of blood or blood products involve a small risk of transmission of diseases such as Hepatitis B (~1 in 800,000), Hepatitis C (~1 in 1,900,000), and HIV/AIDS (~1 in 2,000,000). There is also a small risk of other microbial infections when blood products are transfused.

Alternatives

Blood or blood products are donated by volunteer community donors. These donors are extensively screened about their health history and undergo numerous

blood tests as mandated by the FDA in order to ensure the safest possible blood supply. Other options for the source of blood products are auto-donation (using your own previously donated blood), directed donation (blood donated by people whom you have asked to donate for you), and intra-operative salvage (your own blood collected during surgery) and hemodilution (collecting your own blood early in surgery to be given back to you later). These options may be available if your health, time, and procedure permit. In addition, medications may be used to reduce the need for blood products. You may also choose not to receive blood transfusion; however this decision may hold life-threatening consequences.

Auto-donation is not an option for all patients. Predonation auto-donation involves drawing your own blood prior to a planned surgery for storage in the hospital blood bank. It is important to discuss with your physician if it is safe for you to donate and the likelihood of needing a transfusion given your surgery and current transfusion guidelines. In addition, using your own blood will reduce, but not eliminate, the risk of transfusion-related infections and allergic reactions. Auto-donation may not be available in all areas. Should you choose to make an auto-donation, you should check with your insurance company regarding its reimbursement policy related to this procedure.

If you have additional questions about your

options for blood transfusion, please ask your doctor. You may also contact your local community blood center or hospital transfusion service for more information.

References:

Circular of Information for the Use of Human Blood and Blood Components, AABB. Nov 2013 (revised April 2014)
AABB Technical Manual, 18th Edition.

This brochure was developed by the California Department of Health Services Laboratory Field Services
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In partnership with the Medical Technical Advisory Committee of the Blood Centers of California.

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A PATIENT'S GUIDE TO BLOOD TRANSFUSION

COVER IMAGE

California Department of Health Services

MONTH YEAR

