INVASIVE PROCEDURES PERFORMED IN PATIENTS WHO DECLINE THE TRANSFUSION OF BLOOD PRODUCTS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive maintains policy regarding treatment for patients who, for a variety of reasons, may decline to accept the transfusion of blood products during invasive procedures.

2. SUMMARY OF MAJOR CHANGES: Major changes include:

a. Updated responsibilities for the Department of Veterans Affairs (VA) medical facility Director (see paragraph 5).

b. New responsibilities for VA medical facility health care personnel, ethics consultants at VA medical facility Ethics Consultation Service and chaplains at VA medical facility Chaplain Service (see paragraph 5).

c. Standards and additional considerations for treating patients who are Jehovah's Witnesses (see Appendix B).

3. RELATED ISSUES: None.

4. RESPONSIBLE OFFICE: The Assistant Under Secretary for Health for Clinical Services (11), Surgery Office (11SURG), is responsible for the contents of this directive. Questions may be referred to 202-461-7130 or vhaco.national.surgery.office@va.gov.

5. RESCISSIONS: VHA Directive 1089(1), Invasive Procedures Performed in Patients who Decline the Transfusion of Blood Products, dated July 7, 2014, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of October 2025. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ Kameron Matthews, MD, JD
Assistant Under Secretary for Health
for Clinical Services

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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1. PURPOSE

This Veterans Health Administration (VHA) directive maintains policy regarding treatment for patients who decline to accept the transfusion of blood products during invasive procedures, including invasive diagnostic procedures, interventional cardiology or radiological procedures and operative procedures performed in either the outpatient or inpatient setting. **AUTHORITY:** Title 38 United States Code (U.S.C.) § 7301(b).

2. BACKGROUND

a. VHA supports the patients' right to decline blood products. Some patients decline the transfusion of blood products during or following an invasive procedure for various reasons which include personal or religious beliefs, concern for infectious transmission and potential for transfusion reactions. Some patients decline transfusion despite risking additional illness or death. VHA is committed to the appropriate care and treatment of all patients, regardless of their reasons for declining blood products. Patients who decline blood products may choose to accept administration of blood fractions or blood derivatives. Jehovah's Witnesses are a group of patients who have religious concerns about accepting blood or blood products as part of their medical treatment (see Appendix B for additional information and resources regarding Jehovah's Witnesses).

b. For certain invasive procedures, the anticipated risks without the option of blood product transfusion are to be weighed against the expected benefits in each case. A patient who declines blood products will not be denied appropriate care and treatment.

c. VHA supports Department of Veterans Affairs (VA) health care providers who based on their clinical judgment, conclude that they cannot perform a procedure without the use of blood or blood products because it would be inconsistent with prevailing professional standards.

d. In recent years, medical technological advances have reduced the need for blood product transfusion during, or immediately following, invasive procedures.

3. DEFINITIONS

a. **Allogeneic Blood Transfusion.** Allogeneic blood transfusion is the process of collecting blood from a compatible donor and transfusing the blood into the patient.

b. **Autologous Blood Donation.** Autologous blood donation is the process of donating one's own blood prior to an elective surgical or medical procedure for the purpose of transfusing it into the patient during or after the procedure.

c. **Blood Fraction.** A blood fraction is extracted from blood and may include immunoglobulins and clotting factors (including cryoprecipitate).

d. **Blood Product.** A blood product includes human blood or blood components intended for transfusion. Examples include red blood cells (RBC), white blood cells, platelets and plasma.

e. **Blood Product Derivative.** A blood product derivative is a biologic product that is made from a blood component. These include products such as albumin, clotting factor concentrates and immunoglobulins. These are manufactured products which start with a component from blood, and which may contain a portion of the original product (such as blood proteins) after processing.

f. **Blood Transfusion.** A blood transfusion is the infusion of blood products into a person.

g. **Invasive Procedure.** Invasive procedures include operative procedures in which skin or mucous membranes and connective tissue are incised, or procedures during which an instrument is introduced through a natural body orifice with diagnostic or therapeutic intent.

h. **Patient Blood Management.** Patient blood management is a multidisciplinary clinical approach to optimize the care of patients who may be indicated for transfusion of blood or blood products.

4. POLICY

It is VHA policy that VA health care providers and staff support the Veteran's right to decline blood products and identify medically appropriate options when considering the Veteran for an invasive procedure for which transfusion may be indicated.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Assistant Under Secretary for Health for Clinical Services.** The Assistant Under Secretary for Health for Clinical Services is responsible for:

(1) Supporting the Surgery Office with implementation and oversight of this directive.

(2) Communicating the contents of this directive to each of the Veterans Integrated Service Networks (VISNs) in collaboration with the Assistant Under Secretary for Health for Operations.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the VISNs.

(2) Providing assistance to VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to assure compliance with this directive, relevant standards and applicable regulations.

c. **Director, Surgery Office.** The Director, Surgery Office is responsible for:

(1) Providing VHA oversight of the implementation of this directive.

(2) Maintaining the content of this directive to ensure patients are able to decline blood transfusion and still be considered for invasive procedures.

d. **Veterans Integrated Services Network Director.** The VISN Director is responsible for ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

e. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring that each patient receives appropriate care and treatment even when the patient declines the recommended transfusion of blood products. If the VA medical facility is unable to offer appropriate care and treatment to the patient who declines the recommended transfusion of blood products, the VA medical facility Director should ensure that appropriate care and treatment is provided either through referral to another VA medical facility or from a community care provider through purchased care. ***NOTE:*** *This care should be facilitated through a Third-Party Administrator (TPA). This can be done either through its contracted networks, such as Patient-Centered Community Care (PC3) network, the Community Care Network (CCN) or by establishing a Veterans Care Agreement (VCA).*

(2) Ensuring that appropriate health care providers counsel patients who decline recommended transfusions of blood products for invasive procedures. Counseling should include concepts of patient blood management options as appropriate to the procedure.

(3) Ensuring that treating health care providers recommend medical therapies when patients decline the transfusion of blood products in preparation for surgery or invasive procedures and consider surgical techniques and strategies, including those listed in Appendix A.

(4) Ensuring the VA medical facility's Ethics Consultation Service is available to provide consultation to address ethical concerns and questions or conflict about values, including those between the patient (or authorized surrogate) and the clinical treating team regarding the patient's preferences about recommended blood transfusions or management. ***NOTE:*** *For additional information, refer to VHA Directive 1004.06(2), IntegratedEthics®, dated October 24, 2018.*

(5) Ensuring the VA medical facility's Chaplain Service is available to provide spiritual support to patients who limit or decline blood products or derivatives based on their religious beliefs and preferences about blood transfusions or management.

(6) Ensuring that all VA medical facility staff protects the patient's privacy, taking care to not disclose the patient's decision to decline blood products to others not involved in the patient's care.

f. **Ethics Consultant, VA Medical Facility Ethics Consultation Service.** Ethics Consultants at VA medical facility's Ethics Consultation Service are responsible for providing consultation to patients regarding their preferences for recommended blood transfusions or management, and for responding to ethical concerns and questions, or conflict about values including those between the patient (or authorized surrogate) and the clinical treating team or other staff regarding the patient's preferences about recommended blood transfusions. ***NOTE:*** *For additional information, refer to VHA Directive 1004.06(2)*.

g. **Chaplain, VA Medical Facility Chaplain Service.** Chaplains at VA medical facility's Chaplain Service are responsible for providing spiritual support to patients who limit or decline blood products or derivatives based on their religious beliefs and preferences about blood transfusions or management.

h. **VA Medical Facility Health Care Personnel.** For patients who have declined transfusion of blood products, VA medical facility health care personnel are responsible for:

(1) Providing procedure-specific counseling regarding the use of blood products, blood derivatives and options for patient blood management commensurate with the nature of the intended invasive procedure and associated risks.

(2) Clarifying the distinction between blood transfusion e.g. plasma, platelets, packed red blood cells and blood product derivatives such as albumin, factor concentrates during processes of consultation and informed consent with the patient (or authorized surrogate). Documentation should include the patient's decision of which, if any, blood products or blood management strategies would be acceptable to use. This documentation will be stored in the VA electronic health record.

(3) Discussing with the patient (or authorized surrogate) strategies for care and treatment of a patient's own blood when the patient declines the transfusion of donated blood products and when use of autologous blood collection or autotransfusion is recommended. Options for blood recovery and management should be reviewed with the patient (or authorized surrogate) when they decline transfusion of donated blood products (e.g., cell-salvage, cardiopulmonary bypass).

(4) Discussing with the patient (or authorized surrogate) peri-procedural blood management strategies including medical therapies and pre-procedure autologous donation, and explaining to the patient that medications used to stimulate red blood cell production in the bone marrow may contain human albumin.

(5) Explaining to patients that topical hemostatic agents are frequently used for certain surgical procedures but may be derived from human and animal sources. The religious and cultural beliefs of patients may impact their consent for use of animal-derived products, either generally or for specific animal species. The possible use of topical hemostatic agents with animal-derived products should be disclosed to patients to allow them to make informed decisions. For example, fibrin glue contains a combination of human derived clotting proteins and either bovine thrombin, bovine collagen or equine collagen.

(6) Explaining to patients the risks of the procedure related to the patient's decisions during counseling. The patient's decision following consultation should be fully documented in progress notes and on the informed consent form before undertaking the procedure. ***NOTE:*** *Informed consent must be obtained from patients or their authorized surrogates in a manner consistent with VHA Handbook 1004.01(3), Informed Consent for Clinical Treatment and Procedures, dated August 14, 2009*.

(7) Protecting the patient's privacy, taking care to not disclose the patient's decision to decline blood products to others not involved in the patient's care.

6. TRAINING

There are no formal training requirements associated with this directive.

7. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager or Records Liaison.

8. REFERENCES

a. 38 U.S.C. § 7301(b).

b. VHA Directive 1004.06(2), IntegratedEthics®, dated October 24, 2018.

c. VHA Handbook 1004.01(3), Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009.

d. Jehovah's Witnesses' Position on Allogeneic and Autologous Blood and Flow Chart. *https://www.jw.org/en/medical-library/*.

MEDICAL AND SURGICAL STRATEGIES FOR PATIENT BLOOD MANAGEMENT RELATED TO INVASIVE PROCEDURES

1. GENERAL CONSIDERATIONS

Strategies for consideration by patients who decline blood transfusion include:

a. Evaluation and treatment of anemia, including vitamin and mineral deficiencies, prior to elective procedures. In patients with anemia, allow enough time prior to elective procedures to identify and treat the underlying causes, as appropriate. Consider erythropoietin or iron supplementation to increase red blood cell count.

b. Medical and nutrition/registered dietitian consultations regarding:

(1) Dietary supplementation with exogenous iron, iron rich food sources and food sources or supplements of other applicable vitamins and minerals.

(2) Consideration for increased dietary vitamin C or exogenous supplementation to assure effective iron absorption.

(3) Cessation of all alcohol use at least 7 to 10 days before surgery.

(4) Cessation of over-the-counter herbal or prescribed medications that may hinder or inhibit blood clotting, such as aspirin, ibuprofen and other nonsteroidal anti-inflammatory drugs; anticoagulants such as warfarin, novel oral anticoagulants, antiplatelet medications; vitamin E, Ginkgo biloba, garlic and other natural supplements. Decision to stop such medications/supplements and the time of cessation prior to surgery or intervention should be directed by a health care provider.

(5) Smoking cessation prior to surgical procedures.

c. Administration of medications that reduce bleeding and support coagulation.

d. Reducing the number of blood draws and volume of blood with venipuncture before, during and after surgery.

e. Scheduling non-emergency surgery when hemoglobin levels have reached an optimal range.

f. Encouraging patients to complete an advance medical directive to include specific instructions for the use of blood products or blood derivatives, medications and procedures that are acceptable to the patient.

2. MEDICATIONS

Medications may increase red blood cell production, decrease blood loss or improve oxygen delivery. Certain medications may be prescribed weeks prior to surgery; others

are appropriately used in the perioperative period. These include:

a. Medications to treat acute bleeding including tranexamic acid and aminocaproic acid.

b. Desmopressin to increase certain blood clotting factors.

c. Erythropoietin to stimulate the bone marrow to produce more red blood cells, such as epoetin alfa or darbepoetin alfa.

d. Iron (oral and intravenous).

e. Blood derivatives (if accepted by the patient) to treat bleeding including recombinant activated Factor VII (rFVIIa), anticoagulant reversal agents such as prothrombin complex concentrates (human-derived), or fibrinogen concentrates (human-derived).

f. Topical hemostatic agents such as tissue adhesives or fibrin glue.

3. ANESTHESIA AND SURGICAL TECHNIQUES

a. Certain anesthesia techniques may be implemented to minimize blood loss and optimize patient hemodynamics. These should be individualized depending upon the surgical procedure, patient health status and significant comorbidities. Techniques may include:

(1) The use of pre-procedure autologous blood product collection and transfusion which may be considered for patients who are willing to accept the transfusion of their own blood but not the blood of others.

(2) Administration of volume expanders or intravenous fluids to maintain euvolemia.

(3) The use of acute normovolemic hemodilution (ANH) techniques or blood conservation applications that are implemented by operating room anesthesia providers. These techniques involve collection, dilution and re-infusion of a patient's own blood during a surgical procedure.

b. The following surgical techniques may be recommended by the treating health care provider:

(1) Advanced or minimally invasive surgical procedures to minimize blood loss or to conserve blood during surgery.

(2) Appropriate use of advanced electrosurgery techniques/devices and other hemostatic instrumentation to minimize blood loss during operations.

(3) The use of cell saver or intraoperative blood salvage techniques to collect blood from an active bleeding site and to re-infuse that blood into the same patient, when

permitted by the patient.

(4) The use of blood recovery systems following operation for collection and transfusion of the patient's blood, when permitted by the patient.

JEHOVAH'S WITNESSES

Jehovah's Witnesses are patients who have concerns about accepting blood or blood products as part of their medical treatment. Treating health care providers and Department of Veterans Affairs (VA) medical facilities are encouraged to contact the Hospital Liaison Committee for Jehovah's Witnesses, which is available as a resource to hospital personnel and patients who decline the transfusion of blood products on the basis of the patient's membership in this religion. Arrangements for pastoral care and practical assistance for hospitalized patients can be made through the Hospital Liaison Committee for Jehovah's Witnesses. ***NOTE:*** *To contact the Hospital Liaison Committee for Jehovah's Witnesses, call Hospital Information Services at 718-560-4300. Additional resources can be found on their official website at https://www.jw.org/en/medical-library/.*