PROVIDING MEDICAL TREATMENT WITHOUT BLOOD TRANSFUSIONS

Leading Medical References

September 2022

1. Jehovah's Witnesses actively seek quality medical care. Clinicians in hospitals around the world provide competent surgical and medical treatment without blood transfusions. Such care has even included complex procedures such as organ transplantation[1] and open-heart surgery.[2] This is due to the skill and professionalism of experienced clinicians and hospitals.[3] The various clinical strategies developed to treat anaemia, minimise blood loss, and avoid allogeneic (donor) blood transfusion have been variously referred to as blood conservation, transfusion alternatives, and patient blood management (PBM). As the European Court of Human Rights held in *Jehovah's Witnesses of Moscow and Others v. Russia* (no. 302/02, § 132, 10 June 2010), by refusing consent to blood transfusions in the course of medical care, Jehovah's Witnesses "just make a choice of medical procedures but still wish to get well and do not exclude treatment altogether".

2. The World Health Organization (WHO) recommends that doctors use "alternatives to transfusion" where possible so as not to expose patients (whether adults or children) to the "serious" medical risks associated with blood transfusions and that "[m]ost elective surgery does not result in sufficient blood loss to require a blood transfusion".[4]

3. In recognition of the important role of PBM in promoting patient safety and improving clinical outcomes, in March 2017 the European Commission issued a guide for

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1 Darwish A. Liver transplant in Jehovah's Witnesses patients. *Curr Opin Organ Transplant* 2011;16(3):326-30.

2 Guinn NR, Roberson RS, White W, Cowper PA, Broomer B, Milano C, Chiricolo A, Hill S. Costs and outcomes after cardiac surgery in patients refusing transfusion compared with those who do not: a case-matched study. *Transfusion* 2015;55(12):2791-8.

3 See video, "Transfusion-Alternative Health Care—Meeting Patient Needs and Rights." (produced by Jehovah's Witnesses). Available at: https://www.jw.org/en/medical-library/videos/.

4 World Health Organization. *The clinical use of blood in general medicine, obstetrics, paediatrics, surgery and anaesthesia, trauma and burns.* Geneva: WHO; 2009, pp. 7, 10, 18, 72-73, 126-128, 139-141, 146, 255-258, 262, 264-265 and 272. [ISBN: 9789241545389] [E-ISBN: 978-9240680227] Available at: http://www.who.int/bloodsafety/clinical_use/en/.

national health authorities encouraging the implementation of PBM throughout the EU. The European Commission observed:[5]

> "… a large body of clinical evidence shows that in many clinical scenarios both anaemia and blood loss can be effectively treated with a series of evidence-based measures to better manage and preserve a patient's *own* blood, rather than resorting to a *donor's* blood, thus leading to a significant overall reduction of blood transfusions … This widely accepted approach is referred to as Patient Blood Management (PBM)."
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> "For decades the default treatment for blood loss and/or anaemia has been allogeneic blood transfusion … However, accumulating evidence shows that particularly in haemodynamically stable patients, transfusion is another independent risk factor for adverse outcomes. For example, some systematic reviews and meta-analyses of randomized controlled trials (graded as 1A evidence) have shown some evidence of increased risks (including infection, cardiac events, re-bleeding and in hospital mortality) from liberal transfusion. In addition, large numbers of risk-adjusted observational studies have shown an independent dose-response association between transfusion and increased morbidity, length of hospital stay and mortality." [References omitted.]

4. An analysis of clinical outcomes data from the bloodless medicine program (involving the systematic use of transfusion-alternative strategies to avoid allogeneic blood transfusion) at the John Hopkins Medical Institutions, Baltimore, Maryland, USA, concluded that "using appropriate blood conservation measures for patients who do not accept [allogeneic blood transfusions] results in similar or better outcomes and is associated with equivalent or lower costs". The authors also concluded that the "the lessons learned from bloodless patients can carry over to other patients and lead to a decrease in blood utilization" throughout the medical institution. "These changes not only reduce the cost of patient care, but also may improve outcomes, because transfusion of allogeneic blood has been associated with adverse outcomes in many retrospective studies" (referenced omitted).[6]

5. A study at the internationally respected Cleveland Clinic in Cleveland, Ohio, USA, analyzed outcomes data in a large number of patients who underwent open-heart surgery at their institution over a period of 28 years. The authors of the study used advanced statistical methods to compare the results of cardiac surgery in patients who were Jehovah's Witnesses

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[5] European Commission. *Building national programmes of Patient Blood Management (PBM) in the EU—A Guide for Health Authorities.* Brussels: EU; 2017, pp. 9, 14. [ISBN 978-92-9200-717-1] Available at: https://ec.europa.eu/health/blood_tissues_organs/publications_en.

[6] Frank S, Wick EC, Dezern AE, Ness PM, Wasey JO, Pippa AC, Dackiw E, Resar LMS. Risk-adjusted clinical outcomes in patients enrolled in a bloodless program. *Transfusion* 2014;54(10 Pt 2):2668-77, pp. 2668 and 2675.

with a matched group of non-Witnesses who received transfusion. All patients underwent the same procedures but Witnesses were managed using blood conservation strategies designed to avoid anemia and blood loss. The investigators found that "Witnesses had fewer acute complications and shorter length of stay than matched patients who received transfusions". Moreover, Witness patients "experienced similar or even better short- and long-term survival than non-Witnesses".[7]

6. A large study of 500 Jehovah's Witnesses who underwent open-heart surgery in France concluded that "cardiac surgery without transfusion in high-risk patients such as Jehovah['s] Witnesses can be carried out with results equivalent to those of low risk patients. Recent advances in surgical techniques and blood conservation protocols are main contributing factors".[8]

7. A 2017 study published in *Transfusion,* a leading journal in the field of transfusion medicine, reported on the system-wide results of the systematic implementation of PBM methods in more than 600,000 patients over a six-year period. The study concluded that the PBM approach was associated with "significant" "improvements in patient outcomes, including length of stay, mortality, and hospital-acquired complications" and a financial savings to the health system of up to USD 100 million in "product-acquisition cost" and "activity-based costs of transfusions".[9]

8. In 2019, the authors of a study published in the *Annals of Surgery,* one of the most well-respected journals of surgery, compared the clinical outcomes of surgical patients treated using a simple set of PBM strategies to similar patients undergoing identical procedures in whom no transfusion-alternative strategies were used. A total of 235,779 patients were included in the study. Use of simple PBM strategies resulted in improved patient safety and clinical outcomes (11% reduction in mortality, 20% reduction in major

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[7] Pattakos G, Koch CG, Brizzio ME, Batizy LH, Sabik JF, Blackstone EH, Lauer MS. Outcome of patients who refuse transfusion after cardiac surgery: a natural experiment with severe blood conservation. *Arch Intern Med* 2012;172(15):1154-60, pp. 1154 and 1159.

[8] Vaislic CD, Dalibon N, Ponzio O, Ba M, Jugan E, Lagneau F, Abbas P, Olliver Y, Gaillard D, Baget F, Sportiche M, Chedid A, Chaoul G, Maribas P, Dupuy C, Robine B, Kasanin N, Michon H, Ruat JM, Habis M, Bouharaoua T. Outcomes in cardiac surgery in 500 consecutive Jehovah's Witness patients: 21 year experience. *J Cardiothorac Surg* 2012;7:95, p. 1.

[9] Leahy MF, Hofmann A, Towler S, Trentino KM, Burrows SA, Swain SG, Hamdorf J, Gallagher T, Koay A, Geelhoed GC, Farmer SL. Improved outcomes and reduced costs associated with a health-system-wide patient blood management program: a retrospective observational study in four major adult tertiary-care hospitals. *Transfusion* 2017;57(6):1347-58, pp. 1347, 1352 and 1355.

complications) and reduced costs (average hospital stays shorter by 0.45 days, 39% reduction in the transfusion rate).[10]

9. Mainstream blood conservation and transfusion-alternative strategies include the following, as summarized by the WHO:[11]

- Use of the drug erythropoietin to increase red blood cell level prior to surgery so the patient can tolerate surgical blood losses.
- Use of "blood salvage" technology to recover and reinfuse blood lost during the surgery.
- Use of pharmacologic haemostatic agents to reduce and arrest surgical bleeding.
- Well-planned surgery, meticulous haemostasis and surgical technique to prevent and control any bleeding and thus minimize blood loss and the requirement for blood replacement.
- Use of a lower transfusion threshold than with patients who would consent to blood transfusion.

10. The following excerpts from leading peer-reviewed medical journals confirm that patients who are Jehovah's Witnesses routinely can and do receive quality medical care without blood transfusions. Countless scientific medical reports confirm they fare as well as or in many cases better than patients who receive blood transfusions.

> "Patient blood management programs effectively reduce blood utilization and costs while improving outcomes. Retrospective studies of patients unable to be transfused and undergoing major surgery have shown similar outcomes to matched controls when blood conservation techniques are applied." [References omitted.][12]

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[10] Althoff FC, Neb H, Herrmann E, Trentino KM, Vernich L, Füllenbach C, Freedman J, Waters JH, Farmer S, Leahy MF, Zacharowski K, Meybohm P, Choorapoikayil S. Multimodal patient blood management program based on a three-pillar strategy: a systematic review and meta-analysis. *Ann Surg* 2019;269(5):794-804, pp. 794 and 803.

[11] World Health Organization. *The clinical use of blood in general medicine, obstetrics, paediatrics, surgery and anaesthesia, trauma and burns*. Geneva: WHO; 2009, cited above, pp. 7, 18, 57, 257-258, 262, 264-265 and 274.

[12] Guinn NR, Resar LMS, Frank SM. Perioperative management of patients for whom transfusion is not an option. *Anesthesiology* 2021;134(6):939-48, p. 939.

> "Surgical bleeding contributes to anemia, increases transfusions, and independently increases mortality. In addition, transfusion of allogeneic blood products is associated with increased morbidity and mortality and increased costs, and allogeneic blood products are a limited resource." [References omitted.][13]
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> "Health care systems worldwide have adopted PBM programs enthusiastically, in part because those programs reduce transfusions, lower costs, and have been associated with better patient outcomes."[14]
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> "Providing access to medical therapy for patients who are unable to receive blood transfusion on the basis of religious or other principles is an important clinical challenge. In preparation for meeting the needs of these patients, practitioners should assess whether alternate approaches to medical and surgical management allowing for bloodless care are feasible. On the basis of research with these patients, there is now evidence that blood-sparing strategies can generate outcomes superior to those resulting from the current state-of-the-art management applied to the wider patient population." [Emphasis added; reference omitted.][15]
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> "Increasing evidence suggests that patients have additional adverse clinical outcomes (ie, increased morbidity and mortality) associated with blood transfusions… Patient blood management has been recognised by WHO as a means to "promote the availability of transfusion alternatives". In 2010, blood management was cited as one of the ten key advances in transfusion medicine in the past 50 years." [Emphasis added; references omitted.][16]
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> "Although the safety of blood has improved substantially since the 1980s, when HIV was discovered to be blood transmissible, blood transfusion is an independent risk factor for adverse patient outcomes. Blood transfusions have been associated with increased mortality, increased length of hospital stay related to infections and sepsis, and multi-organ system dysfunction. A recent meta-analysis of 19 prospective, randomised trials comparing restrictive versus liberal transfusions in more than 6000 patients found that adherence to restrictive blood transfusion decreased hospital mortality and postoperative infections."[Emphasis added; references omitted.][17]
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> "The restricted use of allogeneic blood transfusions has been accepted throughout the world as important in reducing risk, particularly of the transmission of infectious diseases. In orthopedic surgery reduced use of

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[13] Spahn DR, Muñoz M, Klein AA, Levy JH, Zacharowski K. Patient blood management: effectiveness and future potential. *Anesthesiology* 2020;133(1):212-22, p. 212.

[14] Zeller MP, Kaufman RM. Safeguarding the patient's own blood supply. [editorial on Mueller] *JAMA* 2019;321(10):943-5, p. 944.

[15] Bracey A. Bloodless cardiac surgery: a strategy for few or the future standard of care? [editorial on Guinn] *Transfusion* 2015;55(12):2773-4.

[16] Goodnough LT. Blood management: transfusion medicine comes of age. *Lancet* 2013;381(9880):1791-2, p. 1791.

[17] Spahn DR, Goodnough LT. Alternatives to blood transfusion. *Lancet* 2013;381(9880):1855-65, p. 1855.

> allogeneic transfusions has been shown to prevent both early and late postoperative infection." [References omitted.][18]
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> "We believe that it is no longer acceptable to maintain a *laissez faire* approach and assume the benefits and accept the risks of allogeneic blood transfusion. Evidence has accumulated questioning RBC transfusion efficacy and establishing transfusion as a contributing risk factor for adverse clinical outcomes in many clinical settings."[19]

11. Respect for patient and parental choice, including medical alternatives to blood transfusions, is a benefit to society. As the above medical references confirm, it has helped to promote effective medical treatment that benefits all citizens, including those who may have no religious objection to blood transfusions.

12. There are significant health hazards associated with blood transfusions, described by the WHO as follows:[20]

- "The transfusion of red cell products carries a risk of serious haemolytic transfusion reactions."
- "Any blood product can become contaminated with bacteria and very dangerous if it is manufactured or stored incorrectly."
- The following infections may be transmitted by transfusion: HIV-1 and HIV-2, HTLV-I and II, hepatitis B and C, syphilis, Chagas disease, malaria, cytomegalovirus (CMV), human parvovirus B19, brucellosis, Epstein-Barr virus, toxoplasmosis, lymes [sic] disease, Creutzfeldt-Jakob disease (CJD) …

13. A comprehensive expert review on blood conservation strategies for use in children published in the journal *Anesthesiology Clinics* states:[21]

> "[T]here remains a small but significant risk of morbidity and mortality associated with any form of blood product administration. … Although in recent years the mainstream media have extensively covered the risks associated with human immunodeficiency virus (HIV) transmission from blood transfusion, there are many other blood-borne diseases, specifically the

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[18] Borghi B, van Oven H. Reducing the risk of allogeneic blood transfusion. *CMAJ* 2002;166(3):332-4, p. 332.

[19] Isbister JP, Shander A, Spahn DR, Erhard J, Farmer SL, Hofmann A. Adverse blood transfusion outcomes: establishing causation. *Transfus Med Rev* 2011;25(2):89-101, pp. 97-98.

[20] World Health Organization. *The clinical use of blood in general medicine, obstetrics, paediatrics, surgery and anaesthesia, trauma and burns.* Geneva: WHO; 2009, cited above, pp. 9-10, 73, 127, 128 and 140-141.

[21] Verma S, Eisses M, Richards M. Blood conservation strategies in pediatric anesthesia. *Anesthesiol Clin* 2009;27(2):337-51, pp. 337-338.

> hepatitides [sic], that have a higher incidence of transmission through transfusion and arguably a greater impact on morbidity and mortality. … The potential immunologic consequences of transfusion are also a major cause of morbidity." [References omitted.]

14. Regarding the use of clinical strategies to avoid blood transfusion in open-heart surgery for infants and small children, clinicians at the internationally renowned Deutsches Herzzentrum (German Heart Institute) in Berlin reported on their 14 year experience in treating congenital heart defects in children of Jehovah's Witnesses. [22] The authors conclude:

> "Bloodless cardiac surgery with and without CPB can be safely performed in Jehovah's Witness infants and children."

15. As far back as 1995, a surgical team at the Albert Starr Academic Center for Cardiac Surgery (affiliated with the Oregon Health and Science University) in Portland, Oregon, USA, published a report about the medical treatment strategies they developed for the safe and successful surgical repair of congenital heart defects in infants without the use of allogeneic blood transfusion.[23] Their clinical outcomes of using transfusion-alternative strategies were so good they wrote:

> "As a result of this intent not to use blood products, they have, in fact, not been required in this experience. . . <u>We have expanded our policy to try to avoid the use of blood products in cardiac operations on infants and children</u> with a body weight of 5 kg or more who need repair of congenital heart defects with CPB and <u>whose parents are not of the Jehovah's Witness faith</u>." [Emphasis added.]

16. The expert medical community has concluded that a "large number" of blood transfusions given to patients are **<u>not</u>** medically necessary.[24,25,26] (S*ee inter alia* the video of

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[22] Alexi-Meskishvili V, Stiller B, Koster A, Bottcher W, Hubler M, Photiadis J, Lange PE, Hetzer R. Correction of congenital heart defects in Jehovah's Witness children. *Thorac Cardiovasc Surg* 2004;52(3):141-6, p. 141.

[23] van Son JA, Hovaguimian H, Rao IM, He GW, Meiling GA, King DH, Starr A. Strategies for repair of congenital heart defects in infants without the use of blood. *Ann Thorac Surg* 1995;59(2):384-8, p. 388.

[24] Shander A, Fink A, Javidroozi M, Erhard J, Farmer SL, Corwin H, Goodnough LT, Hofmann A, Isbister J, Ozawa S, Spahn DR; for the International Consensus Conference on Transfusion Outcomes Group. Appropriateness of allogeneic red blood cell transfusion: the International Consensus Conference on Transfusion Outcomes. *Transfus Med Rev* 2011;25(3):232-46.

[25] Goodnough LT, Maggio P, Hadhazy E, Shieh L, Hernandez-Boussard T, Khari P, Shah N. Restrictive blood transfusion practices are associated with improved patient outcomes. *Transfusion* 2014;54(10 Pt 2):2753-9.

[26] Salpeter SR, Buckley JS, Chatterjee S. Impact of more restrictive blood transfusion strategies on clinical outcomes: a meta-analysis and systematic review. *Am J Med* 2014;127(2):124-131.e3.

the National Blood Authority of Australia: *Blood Transfusions - What is the evidence telling us* at https://www.blood.gov.au/health-professionals.)

17. An analysis of the evidence regarding clinical red blood cell transfusion practice published in the *British Medical Journal* concluded that "published international audits describe inappropriate rates of RBC transfusion of 22-57% in a variety of clinical settings, including hospitalised inpatients, operative units, and emergency departments. Unnecessary blood transfusions may expose patients to harms, including allergic, febrile, or haemolytic reactions; circulatory overload associated with transfusion (seen in up to 1-6% of transfused patients); and acute lung injury. These complications may occur without the transfusion adding any clinical benefit."[27]

18. The World Health Organization (WHO) explains: "evidence from every region of the world indicates considerable variations in patterns of clinical blood use between different hospitals, different clinical specialties and even between different clinicians within the same team. This suggests that blood and blood products are often used inappropriately."[28] The Italian medical journal *Minerva Anestesiologica* reports: "evidence indicates that a great number of the critically ill patients who are being transfused today may not be having tangible benefits from the transfusion".[29]

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[27] Mehta N, Murphy MF, Kaplan L, Levinson W. Reducing unnecessary red blood cell transfusion in hospitalised patients. *BMJ* 2021;373:n830, p. 1.

[28] World Health Organization. *The clinical use of blood in general medicine, obstetrics, paediatrics, surgery and anaesthesia, trauma and burns.* Geneva: WHO; 2009, cited above, p. 9.

[29] Liumbruno GM, Vaglio S, Grazzini G, Spahn DR, Biancofiore G. Patient blood management: a fresh look at a fresh approach to blood transfusion. *Minerva Anestesiol* 2015;81(10):1127-37, p. 1127.