Keck Medical Center of USC

DEPARTMENT OF SURGERY
DIVISION OF HEPATO-BILIARY
& PANCREATIC SURGERY

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Subject: Opinion Regarding Safety and Effectiveness of Transfusion-Free Medical Care

Dear Sir or Madam:

I am Professor of Surgery at the University of Southern California (USC) Keck School of Medicine. My training in Multiorgan Transplantation was at the University of Pittsburgh where the first transfusion-free liver transplantations were performed for Jehovah's Witnesses and published (ref). Eight years later I came to USC to start liver transplant programs at both Keck USC School of Medicine and CHLA (Childrens Hospital Los Angeles). Blood conservation has been a major initiative throughout those years in our division. We have the most robust JW transfusion-free practice in the world with large cohorts of liver, kidney and pediatric liver transplantations as well as complex liver and pancreatic resections. However, the global transfusion-free program at Keck USC has a common platform of quality and practice that supports other divisions and departments- anesthesiology, colorectal, cardiac, thoracic, plastic, urology, gynecology, neurosurgery, foregut, head & neck, and spinal surgery. Many have published their own specialty-specific results. Thus, for those of us at USC, it has been a cultural transformation in both attitudes and practice with respect to blood conservation.

The infrastructure of the Transfusion-Free Medicine and Surgery Program is founded on heightened respect for patient's rights, and core principles that involve thoughtful, compassionate and patient-centered care. Although comprehensive and well-defined policies and procedures are paramount, equally if not more important is having an "ambassador" and/or a staff of liaisons who engage with medical faculty and hospital staff, constituents in the lay community, and of course patients and their families. The duties and responsibilities of these staff liaisons include but are not limited to policy and procedure compliance performed via audits of the electronic medical record; daily rounding; physician referral services; periodic in-service education; and safety and risk mitigation. These functions have greatly increased quality assurance and patient satisfaction.

The Keck Medicine USC Transfusion-Free Medicine and Surgery Program was established 28 years ago. (https://www.keckmedicine.org/centers-and-programs/transfusion-free-care/) Initially, our mission was to offer transfusion free surgical care to Jehovah's Witnesses only. Important initial steps were to: 1) Establish an administrative structure with connection to the Jehovah's Witness community to preserve JW religious identity and beliefs through patient advocacy and in-hospital education, 2) Craft clinical practice policies, derived from existing literature and our own experiences, that allow safe transfusion-avoidance surgical practice, 3) Create internal flow mechanisms for the administrative identification of patients who refuse blood product transfusion i.e. consent forms, unique identifiers, administrative policies & procedures, etc. and 4) Publicly promote the initiative as a safe option for JW patients and cost-saving initiatives for administrators. These initial steps were the important foundation for a broad-based transfusion-free program.

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As the concept of transfusion avoidance matured and gained acceptance within our own program, we expanded its scope to include more difficult cases across all service lines. To date, our transfusion-free JW program has over 2500 complex cases performed in JW without major blood products. These include adult and pediatric heart, liver, kidney transplantations and complex tertiary surgeries. Segments of this data have been published and a comprehensive publication is in progress. Results have been equal or superior to those outcomes in non-JW patients for comparable patient types. While it is true that *some* complex surgeries still may not be possible without transfusion, it is also true that with careful planning and the proper strategy, even the most difficult cases may be performed. Our transfusion-free program is proof of this concept.

Serendipitously, this platform for JW-specific care has found a secular home in patient blood management (PBM) for non-Witness patients. PBM has arisen out of the medically proven benefits of transfusion-avoidance, not upon religious grounds, but for safety and cost reasons. The past three decades have seen countless publications about the benefits of transfusion avoidance. These relate to morbidities & mortalities which are demonstrably higher when patients receive allogeneic blood products[1]. Other outcome measures include infection rates, organ insufficiencies, tumor recurrences, and premature deaths. The major driver of transfusion-related *morbidities* is a phenomenon called TRIM, Transfusion-Related Immunomodulation, and is not related to the safety of blood banking, but rather is inherent in immune mechanisms against foreign substances from blood products administered from a donor source. Thus, the JW resistance to transfusion on religious grounds has logical foundation in the scientific literature as well. These articles have been published in respected journals, and favorable conclusions have been demonstrated across many specialties in surgery, internal medicine, ICU care, and pediatrics[2,3,4]. In our own transplant and hepato-biliary pancreatic surgery division alone, we have published more than 40 articles related to JW surgical care without transfusion.

In the United States the direction and oversight of medicine is moving to embrace blood conservation practice. JCAHO (Joint Committee on Accreditation of Healthcare Organizations) instituted surveillance metrics in 2016 for all hospitals. These metrics focus on anemia, transfusion, and augmentation practices in elective surgical patients. Multi-year institutional data from this study will likely form a basis for institutional ranking and may affect governmental funding of hospitals. On the cost accounting side of the equation lengths of stay, complication rates, and product costs are much more favorable in a transfusion-avoidance population. Thoughtful blood conservation is important for *all* patients- for their own health and for institutional success.

Surprisingly, development of effective blood conservation systems is not difficult. In essence, pre-operative blood augmentation, intra-operative blood conservation with acute normo-volemic hemodilution, and tightly controlled postoperative phlebotomy are essential and quite easy to implement. These techniques alone could likely eliminate the one-two unit transfusions which are so common in non-JW patients in most hospitals. Unfortunately, both clinical practice and transfusion attitudes of physicians remain in the dark ages. The recommended transfusion threshold published in every hospital's transfusion guideline often serves as a transfusion indication rather than a bar that should not be transgressed. Transfusion is casually regarded by most physicians, and the awareness of potential sequelae is not often present. Transfusion-avoidance principles and practice have not made their way into the lexicon or behavior of most physicians.

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Attitudes toward JW patients are often disrespectful and attempts at coercion are common when JW are brought up for surgical consideration. Ironically, the JW have been stalwart in their refusal of blood products and have served as a reliable control group when comparing clinical outcomes in transfused versus non-transfused cohorts. The literature that has proceeded from this comparison is invaluable and has shined a light on the clinical impact of blood product transfusion. The scientific-medical community is hugely indebted to them for their position on blood product refusal.

My final comment would be that safe medical/surgical care and the Jehovah's Witness faith are not mutually exclusive. Recent scientific awareness related to the negative impact of blood product transfusion combined with advances in applied surgical-medical technology make transfusion-avoidance the most sensible choice for a favorable outcome in any patient cohort. The only barrier that remains to broad adoption of a transfusion-avoidance practice is the closed-mindedness of medical practitioners who seem incapable of learning and adopting transfusion avoidance strategies.

Sincerely,

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Randy Henderson
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Relevant Publications

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