1 History and Organization of Blood Management

Blood management has evolved from humble beginnings into a viable, rapidly-developing medical specialty. Its development was initiated by the wish of Jehovah's Witnesses for a transfusion-free treatment and has been shaped by influences coming from transfusion medicine and the military's experiences. Blood management has today been introduced into mainstream medicine. The vivid history of blood management is described in this chapter.

Objectives

1. To identify the historical developments that have led to today's concept of blood management.

2. To demonstrate the benefits of blood management.

3. To identify blood management as "good clinical" practice.

4. To show that blood management and its techniques should be used in all cases who qualify.

5. To help understand how a blood management program works.

Definitions

Bloodless medicine and surgery: Bloodless medicine is a multimodality, multidisciplinary approach to safe and effective patient care *without* the use of allogeneic blood products. Bloodless medicine and surgery utilize pharmacological and technological means as well as medical and surgical techniques to provide the best possible care without the use of donor blood.

Transfusion-free medicine and surgery: Since "bloodless medicine" is something of a misnomer, the term "transfusion-free medicine" was coined and is used instead.

Blood conservation: "Blood conservation is a global concept engulfing all possible strategies aimed at *reducing* patient's exposure to allogeneic blood products" [1]. This concept does not exclude the use of allogeneic blood entirely.

Blood management: Blood management is the philosophy to improve patient outcomes by caring for and managing the patient's own blood as a precious, life-saving resource. It is a patient-centered, multidisciplinary, multimodal, planned approach to patient care. Blood management is not an "alternative" to allogeneic transfusions; it is the standard of care.

Patient blood management: In order to clarify that blood management is not confused with an outcomeoriented transfusion therapy, the term "patient" is added, denoting that it is not the blood in the blood bank that is managed but the patient's own blood that is taken good care of and managed in accord with the philosophy of blood management.

A brief history

Bloodless medicine, transfusion-free medicine, blood conservation, and blood management

The term "bloodless medicine" is often associated with the belief of Jehovah's Witnesses that they should refrain from the use of blood, therefore ruling out the option of

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blood transfusion. The essence of bloodless medicine, and lately, blood management, however, is not restricted to the beliefs of a religious group. To get a better understanding as to what bloodless medicine and blood management mean, let us go back to the roots of these disciplines.

One is not completely wrong to attribute the origin of the term "bloodless medicine" to the endeavor of Jehovah's Witnesses to receive treatment without resorting to donor blood transfusion. Their attitude toward the sanctity of blood greatly influences their view of blood transfusion. This was described as early as 1927 in their journal The Watchtower (December 15, 1927). Although the decision to refuse blood transfusion is a completely religious one, the Witnesses have frequently used scientific information about the side effects of donor blood transfusion to convince their physicians that their decision is a reasonable one and is corroborated by scientific evidence. The booklet entitled Blood, Medicine and the Law of God (published in 1961) explained the Witnesses' religious stand, but also addressed issues such as transfusion reactions, transfusion-related syphilis, malaria, and hepatitis.

Refusing blood transfusions on religious grounds was not easy. Repeatedly, patients were physically forced to take donor blood, using such high-handed methods as incapacitation by court order, strapping patients to the bed (even with the help of police officers), and secretly adding sedatives to a patient's infusion. In the early 1960s, representatives of Jehovah's Witnesses started visiting physicians to explain the reasons why transfusions were refused by the Witness population. They often offered literature that dealt with techniques that were acceptable to Witness patients, informing physicians of the availability of so-called transfusion alternatives. In 1979 the governing body of the Jehovah's Witnesses announced the formation of Hospital Liaison Committees (see Chapter 20). These continued to "support Jehovah's Witnesses in their determination to prevent their being given blood transfusions, to clear away misunderstandings on the part of doctors and hospitals, to establish a more cooperative spirit between medical institutions and Witness patients (our italics)" and to "alert hospital staff to the fact that there are valid alternatives to the infusion of blood". Occasionally, the Witnesses even went to court to fight for their rights as patients. In a great number of cases, the Witnesses' position was upheld by the courts.

Although many physicians had difficulty with the concept of bloodless medicine, some took up the challenge to provide the best possible medical care without the use of blood transfusions. These were in fact the earliest blood managers. As their experience in performing "bloodless" surgery increased, more complex procedures, such as open heart surgery, orthopedic surgery, and cancer surgery, could be performed. Even children and newborns could successfully be treated without transfusing blood. Before long, these pioneering physicians published their results with Witness patients, thereby encouraging other doctors to adopt the methods used in performing such surgical interventions.

Among the first to rise to the challenge was the heart surgeon Denton Cooley of Texas. In the early 1960s, his team devised methods to treat Witness patients. He described the techniques in an article, "Open heart surgery in Jehovah's Witnesses," published in 1964 in *The American Journal of Cardiology*. In 1977, Cooley reported his experiences with more than 500 patients [2].

Cooley's example was followed by many other courageous physicians. For instance, in 1970 Dr Pearce performed bloodless open heart surgery in New Orleans. His efforts did not go unnoticed. Newspapers reported on these spectacular cases. Perhaps out of curiosity or out of the earnest desire to learn, many colleagues visited Dr Pearce's team in the operating room to learn how to do "bloodless hearts." Jerome Kay, from Los Angeles, also performed bloodless heart surgery. In 1973 he reported that he was now performing bloodless heart surgery on the majority of his patients. The call for bloodless treatments spread around the whole world. Sharad Pandey, of the KEM Hospital in Mumbai, India, adopted bloodless techniques from Canada and tailored them to Indian conditions. Centers in Europe and the rest of the world started adopting these advances as well.

It is understandable that Witness patients preferred to be treated by physicians who had proven their willingness and ability to treat them without using donor blood. The good reputation of such physicians spread and so patients from far away were transferred to their facilities. This laid the foundation for organized "bloodless programs." One of the hospitals with such a program was the Esperanza Intercommunity Hospital in Yorba Linda, California, where a high percentage of patients were Witnesses. Herk Hutchins, an experienced surgeon and a Witness himself, was known for his development of an iron-containing formula for blood-building. Among his team was the young surgeon Ron Lapin, who was later famed for his pioneering work in the area of bloodless therapies. Critics labeled him a quack. Nevertheless, he continued and was later honored for opening one of the first organized bloodless centers in the world, as well as for publishing the first journal on this topic, and for his efforts to teach his colleagues. During his career, he performed thousands of bloodless surgeries.

The pioneers of blood management had to rise to the challenge of using and refining available techniques, adjusting them to current needs, and individualizing patient care. They adopted new technologies as soon as was reasonable. Much attention was paid to details of patient care, thus improving the quality of the whole therapy. They also fought for patients' rights and upheld those rights. Many involved in the field of blood management confirm the good feeling that comes from being a physician in the truest sense. There is no need to force a particular treatment. Such an attitude is a precious heritage from the pioneers of blood management. Now, at the beginning of the 21st century, this pioneering spirit can still be felt at some meetings dedicated to blood management.

Currently, strenuous efforts are being made to incorporate blood management further and deeper into mainstream medicine. This elicits various responses. Transfusionists, who are actually well suited to spearhead blood management, sometimes insist that their current realm of activity defines blood management. However, transfusion medicine so far is a discipline in itself and defines only certain aspects of blood management, such as cell salvage or the rare provision of specific, purified blood products, e.g., fibrinogen concentrates. Other aspects of blood management include surgical techniques, pharmacological hemostasis, diagnostic procedures, etc. At the core of blood management, however, is the patient's own blood as a precious, life-saving commodity. To emphasize this further, recently the term blood management has been replaced by the term patient blood management by some groups. Although not all parties agree with the definition of blood management, the World Health Organization (WHO) endorsed blood management as a specialty worth developing further. During its 63rd World Health Assembly in 2010, the WHO defined blood management as the previously published three-pillar model (preoperative anemia management, reduction of blood loss, improvement of anemia tolerance). Although this model includes only one aspect of blood management, the WHO's endorsement represents an important historical development.

Military use of blood and blood management

Over the centuries, the armies of different nations have contributed to the development of current blood man-

agement, but not on religious grounds. Instead, the military made many crucial contributions to blood management by taking care of the thousands of wounded operated on before transfusions became feasible, thereby actually performing "bloodless surgery." It was on the battlefield that hemorrhage was recognized as a cause of death. Therefore, it was imperative for military surgeons to stop hemorrhage promptly and effectively, and to avoid further blood loss. To achieve this, many techniques of bloodless medicine and blood management were invented. The experience of the early surgeons serving near the battlefield is applicable in today's blood management schemes. William Steward Halsted, a surgeon on the battlefield, described uncontrolled hemorrhage [3] and later taught his trainees at Johns Hopkins the technique of gentle tissue handling, surgery that respects anatomy, and meticulous hemostasis (Halstedian principles). His excellent work provides the basis of the surgical contribution to a blood management program.

Since war brought a deluge of hemorrhaging victims, there was a need for a therapy. As soon as transfusions became practical, they were adopted by the military, but experience from the First and Second World Wars also showed their drawbacks, such as storage problems and transfusion-transmissible diseases. So, while the world wars propelled the development of transfusion medicine, they simultaneously spurred the development of alternative treatments. Intravenous fluids had been described in the earlier medical literature [4, 5], but the pressing need to replace lost blood and the difficulties involved in transfusions provided a strong impetus for military medicine to change its practice. In this connection, the following comment in the Providence Sunday Journal of May 17, 1953 is pertinent: "The Army will henceforth use dextran, a substance made from sugar, instead of blood plasma, for all requirements at home and overseas, it was learned last night. An authoritative Army medical source, who asked not to be quoted by name, said 'a complete switchover' to the plasma substitute has been put into effect, after 'utterly convincing' tests of dextran in continental and combat area hospitals during the last few months. This official said a major factor in the switchover to dextran was that use of plasma entails a 'high risk' of causing a disease known as serum hepatitis-a jaundice-like ailment. Not all plasma carries this hazard, he emphasized, but he added that dextran is entirely free of the hazard. 'We have begun to fill all orders from domestic and overseas theaters with dextran instead of plasma."

The military readily adopted other promising products in blood management. For example, the surgeon Gerald Klebanoff, who served in the Vietnam War, introduced a device for autotransfusion in military hospitals. Another example is "artificial blood." Efforts to develop a "blood substitute" were intensified by the US military in 1985, with major investments supporting research at either contract laboratories or military facilities [6]. The driving force for this was not the search for a plasma expander but the search for an oxygen carrier. A third example is the recombinant clotting factor VIIa. Although officially declared to be a product for use in hemophiliacs, the Israeli army discovered its potential to stop lifethreatening hemorrhage and therefore used it in the treatment of injured soldiers.

After the attack on the World Trade Center in New York on September 11, 2001, physicians of the US military approached the Society for the Advancement of Blood Management for advice on blood management. Consequently, specialists in the field of blood management met with representatives of the US military, the result of which was an initiative named STORMACT[®] (Strategies to Reduce Military and Civilian Transfusion). The consensus of this initiative was a blood management concept to be used to treat victims of war and disaster as well as patients in a preclinical setting.

Recently, the military has spearheaded research in the management of massive bleeding and coagulopathy in polytraumatized patients. This research has addressed the immediate application of a tourniquet to a bleeding extremity and the use of hemostatic combat dressings. Military research is even challenging deeply entrenched mnemonics, changing the ABCDE algorithm for trauma care into cABCDE, highlighting the c for catastrophic bleeding as being even more important than airway management.

Transfusion specialists support blood management

Interestingly, right from the beginning of transfusion medicine, the development of blood transfusion and transfusion alternatives was closely interwoven. "Alternatives" to transfusion are as old as transfusion itself.

The first historically documented transfusions in humans were performed in the 17th century and their aim was to cure mental disorders rather than the substitution of lost blood. However, the first transfusion specialists were in fact also the first to try infusions that were later called transfusion alternatives: it was reported that Christopher Wren was involved in the first transfusion experiments as well as being the first to inject asanguinous fluids, such as wine and beer. After two of Jean Baptiste Denise's (a French transfusionist) transfused patients died, transfusion experiments were prohibited in many countries. Even the Pope condemned those early efforts and transfusions ceased for many years.

At the beginning of the 19th century, the physician James Blundell was looking for a method to prevent the death of women due to profuse hemorrhage related to childbirth. His excellent results with retransfusion of the women's shed blood rekindled the interest of the medical community in transfusion medicine. Due to his work with autotransfusion, he was named in the list of the "fathers of modern transfusion medicine." Other physicians followed his example, giving new impetus to transfusion medicine. However, in 1873 Jennings published a report of 243 transfusions in humans, of which almost half of the cases died [7]. Frustration around this situation led some researchers to look for alternative treatments in the event of hemorrhage. Barnes and Little suggested normal saline as a blood substitute [8] and this was introduced into medical practice. Hamlin tried milk infusions [9]. The use of gelatin was also experimented with. One of the advocates of normal saline, W.T. Bull, wrote in 1884 [10]: "The danger from loss of blood, even to two-thirds of its whole volume, lies in the disturbed relationship between the caliber of the vessels and the quantity of blood contained therein, and not in the diminished number of red blood corpuscles; and this danger concerns the volume of the injected fluids also, it being a matter of indifference whether they be albuminous or containing blood corpuscles or not."

In the early 1900s, Landsteiner's discovery of the blood groups was probably the event that propelled transfusion medicine to where it is today. Some 10-15 years later, when Reuben Ottenberg introduced routine typing of blood into clinical practice, the way was paved for blood transfusions. About that time, technical problems had been solved with new techniques and anticoagulation was in use. Russian physicians (Filatov, Depp, and Yudin) stored cadaver blood. The groundwork for the first blood bank was laid in 1934 in Chicago by Seed and Fantus [11], and as already mentioned, the wars of the first half of the 20th century brought about changes in transfusion medicine. Following the two world wars the medical community had a seemingly endless and safe stream of blood at their disposal. Adams and Lundy suggested that the threshold for transfusion should be a hemoglobin level of 10 mg/dL and a hematocrit of 30% [12]. For nearly four decades thereafter, physicians transfused to their liking, convinced that the benefits of allogeneic transfusions outweighed their potential risks.

Over time reports about the transmission of bloodborne diseases increased. In 1962, when the famous article of J.G. Allen [13] again demonstrated a connection between transfusion and hepatitis, an era of increased awareness about transfusion-transmissible diseases began. However, the risk of hepatitis transmission did not concern the general medical community, and it became an acceptable complication of banked blood. It was not until the early 1980s that the medical community and the public became aware of a transfusion-transmissible acquired immunodeficiency syndrome, and the demand for safer blood and "bloodless medicine" increased. Other problems with allogeneic transfusions, such as immunosuppression, added to the concerns. Lessons learned from the work with the Jehovah's Witnesses community were ready to be applied on a wider scale. In the United States, the National Institutes of Health launched a consensus conference on the proper use of blood. Adams and Lundy's 10/30 rule was revised, and it was agreed that a hemoglobin level of 7 mg/dL would be a better transfusion threshold in otherwise healthy patients.

With time, the incentives for effective blood management changed. The immunomodulatory effects of allogeneic blood came to the fore and offered compelling reasons for carefully handling the patient's own blood. The incremental increase of the costs of blood products is another compelling reason for blood management. Lastly, the experience with tens of thousands of patients treated successfully without allogeneic blood transfusions has led some physicians to see allogeneic transfusions having the same fate as the ancient blood-letting.

Blood management today and tomorrow

Currently, there are more than 100 organized bloodless programs in the United States. Many are transitioning to become blood management programs. This is not unique to the United States, since many more programs have been established worldwide. Most were formed as a result of the initiatives of Jehovah's Witnesses, but a growing number now realize the benefits that all patients can receive from this care. The increasing number of patients asking for treatment without blood demonstrates a growing demand in this field. Concerns about the public health implications of transfusion-related hazards have led government institutions around the globe to encourage and support the establishment of these programs. Private and government initiatives have been taken so far that in 2011, the first state-wide blood management program was launched in Western Australia.

The growing interest in blood management is reflected by the activities described below. Major medical organizations (see Appendix B) now include blood management issues on the agenda of their regular meetings. Many transfusion textbooks and medical journals have incorporated the subject of blood management. A growing body of literature invites further investigation (see Appendix B). In addition, professional societies dedicated to furthering blood management have been founded throughout the world (see Appendix B). It is their common goal to provide a forum for the exchange of ideas and information among professionals engaged in the advancement and improvement of blood management in clinical practice and by educational and research initiatives. Clearly, from humble beginnings as an "outsider" specialty, blood management has evolved to be in the mainstream of medicine. It improves patient outcome, reduces costs, and brings satisfaction for the physician-a clear win-win situation. Blood management is plainly good medical practice.

What are the future trends in blood management? As long as there is a need for medical treatment, blood management will develop. Many new drugs and techniques are on the horizon. There are already many techniques available to reduce or eliminate the use of donor blood. It is the commitment to blood management that will change the way blood is used. The authors of this book hope that the information provided by its pages will be another piece in the puzzle that will eventually define future blood management by a new generation of physicians.

Blood management as a program

The organized approach to blood management is a program. These programs are named according to the emphasis each places on the different facets of blood management, such as bloodless programs, transfusionfree programs, blood conservation programs, or global blood management programs. Recently, some programs have been renamed "patient blood management programs." No matter what a hospital calls its program, some basic features are common to all good quality programs, as described below. The step-by-step approach to the development of an organized blood management program is described in Chapter 19.

The administration

The basis for establishing a program is not primarily a financial investment but rather a firm commitment on the part of the hospital. Administrators, physicians, nurses, and other personnel need to be involved, as outlined in the recommendations of the Society for the Advancement of Blood Management. Only the sincere cooperation of those involved will make a program successful.

The heart and soul of a program is its coordinator with his/her in-hospital office [14, 15]. Historically, coordinators were often Jehovah's Witnesses. However, as such programs become more widely accepted, there are an increasing number of coordinators from other backgrounds. Usually, coordinators are employed and salaried by the hospital.

During the initial phases of development of the program, the coordinators may be burdened with significant workload. Together with involved physicians, the coordinator has to recruit additional physicians who are willing and able to participate in the program. Since successful blood management is a multidisciplinary endeavor; specialists from a variety of fields need to be involved. The coordinator needs to meet with the heads of the clinical departments and work toward mutual understanding and cooperation. Each participating physician needs to affirm his/her commitment to the program and to enhance his/her knowledge of the basic ethical and medical principles involved. To ensure a lasting and dependable cooperation between physicians and the program, both parties sign a contract. This contract outlines the points that are crucial for blood management: legal, ethical, and medical issues.

The coordinator is also instrumental for the initial and continuous education of participating and incoming staff. He/she may use in-service sessions, invite guest speakers, collect and distribute current literature, obtain information on national and international educational meetings, and help staff interested in hands-on experience in the field of blood management. Ideally, participating staff members take care of their blood management-related education themselves.

From the beginning of the program, there needs to be a set of policies and procedures. Guidelines for cooperation with other staff members need to be drawn up. It is prudent to have the hospital lawyer review all such documents. Each individual hospital must find a way to educate patients and to document their wishes, to ensure that patients are treated according to their wishes and that these are clearly identifiable. Transfer of patients to and from the hospital needs to be organized. A mode of emergency transfer needs to be established. Procedures already in existence, such as storage and release of blood products and rarely used drugs for emergencies, need to be reviewed. Most probably, available medical procedures in the hospital just need to be adapted to the needs of the program. Additional blood management procedures and devices need to be introduced to the hospital staff. The use of hemodilution, cell salvage, platelet sequestration, autologous surgical glue, and other methods needs to be organized. Besides, departments not directly involved in patient care can contribute to the development of policies and procedures. This holds true for the administration offices, blood bank, laboratory and technical departments, pharmacy, and possibly the research department. There is also a variety of issues that need legal and ethical clarification. In keeping with national and international law, issues concerning pediatric and obstetric cases need to be clarified well before the first event arises. Forms need to be developed and a protocol for obtaining legal consent and/or advance directive must be instituted.

To assure continuing support on the part of the administration and the public, some measures of quality control and assurance need to be implemented. Statistical data from the time before the establishment of a certain procedure should be available for comparison with those obtained after its institution and during the course of its implementation. These data are a valuable instrument to demonstrate the effectiveness of procedures and their associated costs. They also serve as an aid in decisionmaking regarding possible and necessary changes. If records are kept up-to-date, developments and trends can be used as an effective tool for quality assurance and for the identification of strong and weak points in a program. Such records are also helpful for negotiations with sponsors and financial departments, discussions with incoming physicians, and public relations.

The coordinators, and later their staff, need to be well informed about policies and procedures in their hospital and the level of care the facility can provide. There may be times when the burden of cases or the severity of a patient's condition outweigh the faculty's capacity or capability. In such cases, a list of alternative hospitals better suited to perform a certain procedure should be available.

Good communication skills are essential for the daily activities of the coordinator since he/she is the link between patients and physicians. The coordinator is in constant contact with the patient and his/her family and is involved in the development of the care plan for every patient in the program. The coordinator informs the staff involved in the care of the patient about issues pertaining to blood management. In turn, staff members inform the coordinator about the progress of the patient. Planned procedures are discussed and any irregular development is reported. Thus, developing problems can be counteracted at an early stage, thereby avoiding major mishaps.

There is virtually no limit to the ingenuity of a coordinator. He/she is a pioneer, manager, nurse, teacher, host, helper, and friend. No successful program is possible without a coordinator.

The physician

Several studies on transfusion practice in relation to certain procedures demonstrate a striking fact: A great institutional variability exists in transfusion practice, for no medical reason. For example, in a study on coronary bypass surgery the rate of transfusions varied between 27% and 92% [16]. What was the reason? Did those physicians who transfused frequently care for sicker patients? No, the major differing variable was the institution—and with it the physicians. This is in fact good news. If a physician's behavior can be modified to appropriately limit the transfusion rate, then a blood management program can effectively reduce the number of transfusions.

Basic and continuous education is crucial for physicians participating in a blood management program. To start with, physicians should intercommunicate about currently available techniques of blood management that relate to their field of practice and compare their knowledge and skills with those of others. This honest comparison will identify the strong and weak areas in a physician's practice of blood management. Then, new approaches, techniques, and equipment should be added as needed. However, remember that not all techniques suit all physicians and not all physicians suit all techniques. After all, it is not a sophisticated set of equipment that makes for good blood management-it is a group of skilled physicians. That is why it is desirable that all physicians in a blood management program be aware of the experiences and skills of their colleagues, in order to make these available to all patients.

Another group of professionals that is essential for the program to succeed are the nurses. Nurses play a vital role as they contribute much to patient identification, education, and care. Nursing staff must therefore also be included in the process of initial and continuing education.

Commitment, education, cooperation, and communication are key factors for a successful blood management program. To make each treatment a success, it requires the concerted effort by physicians, coordinators, nurses, administrators, and auxiliary staff on the one hand, and the patient with his/her family on the other.

Key points

• Blood management is a good clinical practice that should be applied to all patients.

• Blood management is best practiced in an organized program.

• Blood management improves outcomes, and is patient centered, multidisciplinary, and multimodal.

• Respect for patients, commitment, education, cooperation, and communication are the cornerstones of blood management.

Questions for review

1. What role did the following play in the development of modern blood management: Jehovah's Witnesses, physicians, the military, and transfusion specialists?

What do the following terms mean: bloodless medicine, transfusion-free medicine, blood conservation, blood management, and patient blood management?
What are the important facets of a comprehensive

blood management program?

Suggestions for further research

1. What medical, ethical, and legal obstacles did early blood managers have to overcome?

- 2. How did they do this?
- 3. What can be learned from their experience?

Exercises and practice cases

Read the article by Adams and Lundy [12] that builds the basis for the 10/30 rule.

Homework

Analyze your hospital and answer the following questions:

1. What measures are taken to identify patients for blood management?

2. What is done to comply with legal requirements when documenting a patient's preferences for treatment?

3. What steps are taken to ensure a patient's wishes are heeded?

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