

## IMPLEMENTATION AND EXECUTION OF CIVILIAN REMOTE DAMAGE CONTROL RESUSCITATION PROGRAMS

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**ABSTRACT**—Remote damage control resuscitation is a recently defined term used to describe techniques and strategies to provide hemostatic resuscitation to injured patients in the prehospital setting. In the civilian setting, unlike the typical military setting, patients who require treatment for hemorrhage come in all ages with all types of comorbidities and have bleeding that may be non-trauma related. Thus, in the austere setting, addressing the needs of the patient is no less challenging than in the military environment, albeit the caregivers are typically not putting their lives at risk to provide such care. Two organizations have pioneered remote damage control resuscitation in the civilian environment: Mayo Clinic and Royal Caribbean Cruises Ltd. The limitations in rural Minnesota and shipboard are daunting. Patients who have hemorrhage requiring transfusion are often hundreds of miles from hospitals able to provide damage control resuscitation. This article details the development and implementation of novel programs specifically designed to address the varied needs of patients in such circumstances. The Mayo Clinic program essentially takes a standard-of-care treatment algorithm, by which the patient would be treated in the emergency department or trauma bay, and projects that forward into the rural environment with specially trained prehospital personnel and special resources. Royal Caribbean Cruises Ltd has adapted a traditional military field practice of transfusing warm fresh whole blood, adding significant safety measures not yet reported on the battlefield (see within this Supplement the article entitled “Emergency Whole Blood Use in the Field: A Simplified Protocol for Collection and Transfusion”). The details of development, implementation, and preliminary results of these two civilian programs are described herein.

**KEYWORDS**—Shock, prehospital, trauma, shipboard, helicopter, whole blood, TXA

### INTRODUCTION

Remote damage control resuscitation (RDCR) is essentially defined as the concept of damage control resuscitation applied in prehospital care, likely most important in austere situations in which, traditionally, blood products and robust resuscitative capability have not existed. This article describes the development and implementation of two such RDCR programs in civilian environments: one at Mayo Clinic Trauma Center (inclusive of Mayo Clinic Medical Transport) and the other aboard Royal Caribbean Cruises Ltd (RCCL) cruise ships.

#### **Identification of the need for a civilian RDCR program**

Early and aggressive use of blood components has become the standard of practice for the management of traumatic hemorrhagic shock and the deleterious effects of primary and secondary coagulopathy that develops in the majority of severely injured trauma victims. The prehospital resuscitation of the exsanguinating patient with trauma is time and resource dependent. Rural and maritime hemorrhage care (medical and injury causes combined) magnifies these factors because transportation time to definitive care is increased. The combination of damage

control resuscitation with emphasis on early plasma delivery and the location of definitive care centers remote from initial resuscitation in the rural environment or aboard ship have led to the development of RDCR programs in those settings. Austere environment applies just as well in civilian settings as it does in military settings, as in contrast to the short prehospital transit time in most civilian urban trauma centers, the geographic expanse of the rural landscape or the maritime environment leads to inherent delay in the care of the hemorrhaging patient. Even in the presence of a mature regional rural trauma system and robust ship-to-shore evacuation, the care of a patient in shock is limited by the timing and effectiveness of resuscitation in those remote areas.

Aggressive replacement of coagulation factors with plasma is a crucial hemostatic resuscitation component of effective massive transfusion protocols (MTPs). Because of the necessity to transfuse plasma early and often in the severely injured, the lag time associated with the thawing and provision of fresh frozen plasma (FFP) hampers such efforts. Massive transfusion protocols have evolved to rely on the rapid availability of thawed plasma (TP) for use in hemostatic resuscitations (1).

#### **The rural trauma center and helicopter emergency medical services experience in Minnesota**

To address the early resuscitation needs and trauma-induced coagulopathy in the exsanguinating patient with trauma, an RDCR strategy was developed that involves prehospital TP-first transfusion protocol, and the use of tranexamic acid (TXA) was

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developed and implemented as an extension of the MTP already in place in our trauma center. As the only American College of Surgeons–designated level I trauma center within our region, we serve a catchment area of 18,600 sq mi encompassing 30 referring hospitals. Of these 30 hospitals, no facility has on-site TP available, and only three (10%) have on-site FFP. This “geographic plasma deficit” is magnified by our mean transport time being 40 min. The extension of a field-ready blood bank by way of our helicopter emergency medical service (HEMS) transport allows availability of level I resuscitative resources in these remote locations (2).

### **Blood bank background at Mayo Clinic**

Fresh frozen plasma that has been thawed and stored at refrigerated temperatures (1°C–6°C) can be converted to TP if the original plasma product was collected using a closed system. Thawed plasma production was implemented at our institution to better respond to patients who require the rapid provision of plasma transfusions (e.g., massive transfusion patients). Ideally, hemostatic resuscitation is conducted using plasma that is ABO-identical with the patient. However, with the advent of aggressive, early coagulation factor replacement in trauma victims, plasma transfusions are often administered before the determination of the patient’s ABO type. Historically, group AB plasma, because it does not contain anti-A or anti-B isoagglutinins that react against A or B antigens on recipient red blood cells (RBCs), has been considered the “universal plasma donor.” Unfortunately, blood group AB is present in only 4% of the white population in the United States (3). This reality poses a serious supply-versus-demand issue (i.e., inadequate supply of AB TP) as early hemostatic resuscitation of trauma victims becomes increasingly utilized.

To successfully implement a prehospital plasma program, it was necessary to answer the question as to whether emergent transfusion needs could be met through the use of group AB “universal donor plasma.” At Mayo Clinic, which has its own donor center and manufactures its own plasma products, the number of AB plasma products produced on an annual basis was determined to be inadequate to support the rotating stock of TP necessary to continuously supply our blood storage refrigerators in the emergency department (ED) and the HEMS. Because of an inadequate supply, it was decided that AB TP to support our emergency transfusions was not an option.

To mitigate the risk of transfusion-related acute lung injury (TRALI), many institutions have adopted the approach of transfusing plasma products that are predominantly collected from male blood donors (predominantly male plasma). The American Red Cross recently published information on the residual risk of TRALI from plasma transfusions for the years 2008 to 2011 following implementation of the TRALI mitigation strategy of providing predominantly male plasma for transfusion (4). The American Red Cross plasma distributions from male donors currently exceed 99% for blood groups A, B, and O, but it is only about 60% for blood group AB. In 2006, before TRALI mitigation, the rate of suspected TRALI was 18.6 cases per million distributed plasma units. Overall, from 2008 to 2011, post-TRALI mitigation, the rate of suspected TRALI was 4.2 cases per million distributed units ( $P < 0.0001$ ). The

suspected TRALI rate for AB plasma post-TRALI mitigation was unchanged at 26.3 cases per million distributed units, and this was significantly higher than the 2008 to 2011 rates for A, B, and O plasma (1.8 per million units; odds ratio, 14.5; 95% confidence interval, 6.8–30.9). The continued need for AB plasma from female donors results in an increased risk of TRALI with this product.

The provision of predominantly male AB plasma in support of the early hemostatic resuscitation of trauma patients is likely to be unsustainable from a supply perspective. If, to attempt to meet demand, female as well as male AB plasma is used for hemostatic resuscitation, then trauma victims will be exposed to a genuinely increased risk of TRALI. Therefore, in addition to there being a much more readily available supply, group A plasma, because it is a predominantly male product, poses a significantly decreased risk of TRALI. In contrast, the risk of hemolysis mediated by the transfusion of anti-B to patients who are blood group B or AB is only a theoretical, potential risk.

Recently, the anti-B titer range of the A plasma donors was determined at our institution to assess the potential risk of hemolysis in a B or AB individuals receiving group A plasma transfusions (5). Anti-B titers were performed on 120 group A male donors from the blood donor pool at our facility. Serial dilutions of donor serum and saline were prepared using a Freedom Evo (TECAN Group, Ltd, Männedorf, Switzerland). Commercially prepared (Bio-Rad, Hercules, CA) 3% A1 RBCs were added to all tubes. The tubes were incubated for 30 min at 37°C, washed three times, and macroscopically read for agglutination at the anti-human globulin phase. The titer was concluded to be the highest dilution revealing a reaction strength of 1+ agglutination. The median anti-B titer was 16, no donor had an anti-B titer result greater than 512, and 91.7% of the donors had a titer of 64 or less. This serologic data showing predominantly low titers of anti-B in our male plasma donors are congruent with our clinical experience that the use of group A plasma for emergent transfusions in patients with unknown blood types is a safe practice.

In 2008, a TP program was implemented at our institution for use in patients requiring rapid coagulation factor replacement. This was based on review of the literature supporting early use of plasma in a 1:1 ratio and required extensive discussion amongst trauma program leadership, emergency medicine and nursing leadership, blood banking leadership, and transfusion medicine leadership. A comprehensive process allowing for the immediate use of pre-TP was designed by the Transfusion Medicine service. Fresh frozen plasma is thawed, labeled, and initially stored as plasma product with a 24-h outdate (FP) in refrigerated storage (1°C–6°C). If the FP is not transfused before the 24-h outdate, the product is converted to TP, which extends the duration of acceptable refrigerated storage for an additional 4 days. A report from our laboratory information system allows us to track the expiration dates of our FP and TP to ensure that these products are transfused before expiration. Group A TP is used for emergent transfusions in patients with unknown blood types. Based on published ABO phenotypes in the white population, for example, it would be predicted that group A plasma transfusion in a patient with an unknown blood type would be compatible in 87% of cases (3). No cases of

hemolysis related to the emergent use of group A plasma have been documented at our institution since the implementation of TP program.

Thawed plasma is used in our institution to achieve two important goals. The first goal is to decrease the time necessary to make plasma products available for transfusion, and the second goal is to decrease the amount of plasma discarded because of storage time expiration. A study from 2010 at Mayo Clinic looked at the effect of TP on the amount of discarded plasma products (6). Before TP implementation, between January and June 2008, 427 U of FFP were discarded. In 46.4% of cases, the FFP units were discarded because they were not transfused before the 24-h expiration time. In July 2008, the FFP conversion to TP was implemented. Between January and June 2009, 394 plasma products were discarded. Only 13.7% of these units were discarded because of not being transfused before the 5-day expiration time.

In July 2009, Mayo Clinic began stocking the ED and helipad refrigerators with group A TP from male-only donors. The prehospital plasma protocol at our institution was the result of a collaborative effort involving MCMT Air Operations, the Trauma Service, and the Division of Transfusion Medicine. Incorporation of TP into the HEMS was the culmination of an 18-month process. The general philosophical approach used is that once a standard of care is established in the ED, if it is feasible to adopt that practice in the prehospital environment, it will be adopted. Point-of-care laboratory testing using i-Stat (Abbott, Princeton, NJ) is used to obtain hemoglobin, base deficit, lactate, and potentially international normalized ratio (INR; currently in validation due to vibratory environment) for patients evacuated from the scene, whereas baseline laboratory values completed at the referring hospital can be used for patients being transferred to the trauma center. These are key elements in the transfusion trigger algorithm (Table 1). Initially, every HEMS flight carried a cooler containing 4 U of RBCs (O negative) and 2 U of TP (group A). Subsequently following assessment of the overall goals and strategies of hemostatic resuscitation, the HEMS now carries 3 U of RBCs and 2 U of TP. Blood products are used as the primary source of volume expansion. Any plasma products stored in the ED or helipad refrigerators that are removed and transfused are restocked upon notification of the transfusion service. To prevent

the outdated of the TP units carried by the HEMS, non-transfused units are returned to the inventory of the transfusion service on day 3 after thawing and replaced with younger thawed units in a preplanned "unit cycling" process. Thawed plasma units not used by the ED or HEMS are subsequently put into general blood inventory to meet the transfusion needs of other patients at our institution. In a study reporting on the use of prehospital plasma transfusions for the reversal of warfarin in patients with traumatic brain injury (7), more than 2,500 U of plasma were transported on 2,836 flights, and 27 U of TP were transfused to 16 patients. All unused plasma units carried on the flights were reentered into the blood product inventory of the transfusion service and subsequently transfused to patients requiring plasma transfusions. No hemolytic transfusion reactions resulted from the administration of prehospital group A plasma.

A review of all trauma patients receiving emergency group A plasma transfusions from 2008 to 2011 was recently conducted at our institution (8). Of 254 patients, 219 (86%) received ABO-compatible plasma, and 35 (14%) received ABO-incompatible plasma. There were no hemolytic transfusion reactions in the patients receiving ABO-incompatible plasma, and there were no differences in mortality or overall complications in patients receiving ABO-incompatible versus ABO-compatible plasma.

The use of blood group O RBCs for emergent transfusions has also proven to be a safe practice at our institution. We recently evaluated all emergency release group O RBC transfusion episodes from January 2006 through December 2010 (9). During this period, there were 4,144 U of RBCs emergently released during 1,444 transfusion episodes. Adverse reactions were reported in 18 patients with no acute hemolytic reactions. There were six febrile nonhemolytic transfusion reactions, two episodes of circulatory overload, six allergic reactions, three delayed serologic reactions, and one delayed hemolytic reaction, for an overall rate of hemolysis secondary to emergency release group O RBCs of less than 0.1%.

### **Making the process work**

Development of prehospital care protocols for damage control resuscitation includes involvement of all of the stakeholders. These need to match the protocols and care provided in the ED, operating room, and intensive care unit (ICU) settings. Guidelines have already been written for the recognition of shock using a combination of physiologic factors and clinician judgment and action required (MTP) to resuscitate the patient. Hospital quality programs and performance improvement programs provide oversight of appropriate use and success of MTPs. Adoption of such hospital-based protocols then allows for the extension of these protocols to affect early RDCR. Ongoing education and training as well as review and update of the protocols will keep them relevant and provide the most up-to-date care for patients in the field.

Oversight of prehospital critical care transport requires three crucial components: (a) hospital-based or affiliated program, (b) protocol development, and (c) medical direction. Being a hospital-based or affiliated program allows for appropriate recruitment, training, and education of the prehospital personnel. It also builds a strong working relationship with the key stakeholders, in this case blood bank personnel, ED, operating room

**TABLE 1. Mayo clinic HEMS treatment for hemorrhagic shock transfusion triggers**

Blood product administration is indicated for treatment of hemorrhagic shock. Blood products should be administered if an adult patient has two of the following:

1. Hypotension (single systolic blood pressure  $\leq 90$  mmHg)
2. Tachycardia (single heart rate  $\geq 120$  beats/min)
3. Penetrating mechanism
4. Lactate  $\geq 5.0$  mg/dL
5. INR  $\geq 1.5$
6. Base deficit  $\geq 5$
7. Evidence of bleeding or decreasing hemoglobin, clinician judgment

environment, and surgical ICU. Without this intricate working relationship, implementation of protocol development becomes challenging to the point of insurmountability.

Robust medical direction is crucial for recruitment and education of the prehospital care providers as well as ongoing education. Critical review of prehospital care relates to appropriateness of transport, quality of care provided, and opportunities for improvement. Implementation and oversight of prehospital care guidelines for hemorrhagic shock conditions allow for seamless transition of care from the field to the hospital.

Training of new employees is composed of hands-on in-depth education with a preceptor and individual practice. Ongoing training or practice opportunity for all staff is available throughout the year. One or more of the hemostatic agents used in our program are included in annual skills testing in which all staff are tested on equipment and skills critical to the care of critically ill and injured patients.

Process improvement is done through medical director record review. All flight records are reviewed for appropriateness of care and/or deviation from our guidelines, and feedback on this review is given to the flight crew at the monthly flight team meeting. Select records are reviewed with all staff to reinforce the decreased use of crystalloid and appropriate use of blood products. Through these reviews, we have uncovered small challenges such as the infrequent use of TXA. We found that because of our short flight times, packed RBCs (PRBCs) and plasma were still infusing, and there was no dedicated intravenous line available to infuse the TXA. Since employing TXA in our HEMS in July 2012, we have administered it more than 20 times (half of the cases are nontrauma), and all are receiving TP, whereas some are also receiving PRBCs; many patients are outside the 3-h time frame since injury and have been excluded from administration.

Over the past 3 years, our HEMS program has transfused PRBCs to more than 300 patients (majority nontrauma by 2:1 ratio) and transfused plasma to more than 350 patients (majority trauma or spontaneous intracranial hemorrhage for warfarin reversal); the mean number of units transfused per patient is 2 U of PRBCs and 2 U of TP. Also through the reviews, we have noticed appropriate and increasing use of hemostatic adjuncts (hemostatic gauze) and tourniquets. In some instances, tourniquets are being applied by true first responders, for example, law enforcement personnel, before HEMS arrival. Our HEMS team has used hemostatic dressings since December 2011, and there have been more than 50 patients treated with nearly universal success in hemorrhage control. In cases where it has not been successful, the addition of a tourniquet has been undertaken. The numbers of tourniquets used, beginning in June 2009, and used in more than 50 patients (a few were used to augment hemostatic dressings) were also nearly universally successful in achieving hemorrhage control. This is currently under study to determine the exact value and appropriate use of these hemostatic adjuncts.

All of this is then followed through at the hospital level via a formal performance improvement process. This involves the blood bank, transfusion services, the transfusion committee, and the trauma services. Appropriate compliance with the MTP triggers and protocol are closely monitored. Likewise, any

untoward outcome for any patient receiving RDCR is closely scrutinized for opportunities for improvement.

### ***The maritime environment and development of RDCR***

Steve Williams, RN, CEN, CRFN, director of Fleet Medical Operations for RCCL, presented a fascinating summary of the development and implementation of an RDCR on cruise ships at the THOR (The Hemostasis and Oxygenation Research Network) symposium in June 2013. Uncontrolled bleeding, particularly from the gastrointestinal tract, is a feared condition at sea. The cruise industry is seeing more catastrophic nontraumatic bleeding events related to the increased use of antiplatelet agents such as clopidogrel in combination with acetylic acid and increased use of anticoagulation with warfarin. Even on cruise ships, surgical options are limited, and safe blood for transfusion is not readily available in the ports that the ships visit. Recently, RCCL has provided their vessels with equipment to perform blood transfusions for patients who are continuing to bleed despite conservative therapy for the transfusion of up to 4 U of warm fresh whole blood (WFWB) from available donors on board beginning in June 2010. The demographics in this environment are intriguing. Depending on the vessel used, the average 7-day cruise will host up to 6,300 guests. On any given day, with 34 ships in their fleet, RCCL can have nearly 100,000 guests on the water, tended to by 37,000 crew members and a medical staff of 74 physicians and 127 nurses. All ships in the RCCL fleet have an ICU bed, with fairly comprehensive laboratory support, including the ability to do a complete blood count, white blood cells, and platelets. All RCCL ships can also run a prothrombin time/INR using an i-Stat clinical analyzer.

In their practical analysis of medical needs, RCCL determined they needed a solution for severe hemorrhage for ships that were more than 24 h from a port. Storage of O negative blood is impractical and would be a waste of a valuable resource; plasma expanders have limited benefit, and timely surgical intervention is not possible. Consensus was achieved that transfusion and the use of hemostatic adjuncts would only be used in life-threatening circumstances when a patient was likely to die without intervention before evacuation.

Thus, an RDCR program was born out of necessity. Two hundred fifty medical personnel were trained on a newly developed RDCR transfusion protocol, which incorporates WFWB as the mainstay for lifesaving transfusions. A transfusion kit was assembled, and an algorithm created. The kit included citrated blood collection bags, Eldon cards (Craig Medical, Vista, CA) for blood grouping, rapid screening tests for HIV and hepatitis, and appropriate written guidance as a reference. One of the key features is the early identification of the need for transfusion and appropriate consent of the patient. Consent involves education of the patient as the dire circumstances, austere environment, and risk of death with or without transfusion before evacuation. The shipboard physician is required to discuss the need for transfusion with an on-call senior clinician, before starting the transfusion. Perhaps the most unique feature of the program is the prioritization of the donors. In order of preference, RCCL chooses sexual partners, assuming they are compatible donors; guests with known blood donor cards; guests

who are blood donors without cards; medical team members; and finally the crew. Family members were initially included in the protocol, but with the increased likelihood of graft-versus-host-disease, family members were later excluded from the donor protocol. Similarly, consideration is being undertaken for the limitation of female donors due to the concern for TRALI. In several cases where patients were in critical condition, and there was limited time to round up passenger donors, the first unit of blood was donated by a member of the medical team.

Over a 40-month period following implementation of this RDCR program, RCCL studied the effects of transfusion on 37 guests and three crew members. At initial presentation, hemoglobin values ranged from 4 to 10.6 g/dL with a mean of 5.96 g/dL. Units of fresh whole blood transfused ranged from 1 to 6 U. Four patients were lost to follow-up, six patients eventually died of their disease (none related to transfusion), no patients exhibited seroconversion with a transfusion transmissible disease at 12-month follow-up, and there was one potential transfusion reaction, which was thought likely to be an allergic reaction. One of the key features brought out in the review process was the importance of transfusion end point being appropriate perfusion (hemodynamic parameters), not an arbitrary hemoglobin value. There is also strong emphasis on the use of TXA, reversal of warfarin if the patient is taking it, and limiting the amount of crystalloid given to these hemorrhage patients. Blood transfusion on cruise ships is complicated and hazardous, should only be done for patients in a critical condition who have failed conservative therapy, but may in selected cases be lifesaving.

Although the RCCL approach to hemorrhage has been successful and contains lessons for resuscitation of hemorrhagic shock in austere environments, there are severe limitations that prevent implementation of such a protocol once at port. Warm fresh whole blood is not recognized by the US Food and Drug Administration (FDA) as a blood product. While cruising international waters allows RCCL to avoid this bureaucracy, there are multiple, important reasons that prevent the FDA from approving WFWB; transfusion-transmitted diseases (TTDs) are paramount among these concerns. Current guidelines for blood product infectious disease screening include testing for HIV, hepatitis B virus, hepatitis C virus, West Nile virus, human T-lymphotropic virus types 1 and 2, and syphilis. Rapid nucleic acid and serologic tests for these TTDs are not available at the point of care. In addition, ship-wide testing of a pre-screened donor pool is impractical, given the rapid and large turnover in passengers. A rapid HIV test has recently been FDA approved but is not sufficiently definitive for blood product transmission (10). In addition, pathogen reduction technologies are not currently feasible for use in the austere environment. The largest reported experience with WFWB is from Operation Enduring Freedom and Operation Iraqi Freedom with more than 10,000 U transfused, demonstrating a low, but present, risk of TTD transmission including one documented case of hepatitis C virus and one human T-lymphotropic virus type 1. Although low, this rate represents a substantially greater risk than civilian blood product transfusions (11, 12). Further logistic concerns against widespread implementation of WFWB programs include the need for definitive blood

typing as there is no widely accepted universal whole blood donor. Therefore, a rapid and reliable blood typing mechanism must be in place. Most American hospitals will not transfuse based solely on Eldon card blood type results because of the increased risk of a hemolytic reaction secondary to an incompatible transfusion. Lastly, the risk of microchimerism and graft-versus-host disease is greater with younger pRBC transfusions. As the youngest form of RBCs, WFWB likely carries an increased risk as well.

When treating a bleeding patient in the austere environment, the risks of TTDs, incompatible transfusions, and graft-versus-host disease must be weighed against the 30% risk of death from massive hemorrhage (13). These risks of WFWB, although potentially severe, are diseases of survivorship, which require the patient to survive the initial hemorrhage insult to develop.

### The future

Clearly, outcomes research needs to be done to validate the indications for RDCR in the civilian environment and the best practices to fit the needs of the patients in those remote settings. Further work is being done in Norway to include nationwide HEMS use of freeze-dried plasma (implemented in HEMS base Bergen in April 2013) and RBCs. Leukoreduced (using Terumo Imuflex [Lakewood, CO] platelet-sparing filter), fully tested, refrigerated, stored whole blood will be introduced both in the university hospital and HEMS base in Bergen, Norway, as soon as the practical issues have been solved. The cold-stored whole blood will be utilized within 7 to 10 days of storage. At Mayo Clinic, we have a plan to implement room temperature platelets in HEMS, refrigerated stored whole blood in the trauma center, and likely refrigerated platelets in both environments in a step-wise fashion.

## CONCLUSIONS

Remote damage control resuscitation in the civilian setting is a necessity in the austere environment for people with severe hemorrhage to prevent loss of life. Programs can be established to provide lifesaving resuscitation in these environments with careful, deliberate, and thoughtful planning. As these are new practices, they must be carefully and formally studied to demonstrate not only safety and efficacy but also feasibility and cost-effectiveness. This will be the focus of the work of the THOR Network for the next decade. Paramount to the success of civilian RDCR programs is close coordination and collaboration among experts in transfusion medicine, blood banking, education, and critical care of the ill and injured. The use of hemostatic resuscitation, hemostatic adjuncts (both injectable and mechanical), and even the use of WFWB may be necessary to carry out a successful program. The medical oversight, including tight performance improvement vigilance, is of necessity if one wants not only to save lives but also to first do no harm.

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