Give the trauma patient what they bleed, when and where they need it: establishing a comprehensive regional system of resuscitation based on patient need utilizing cold-stored, low-titer O+ whole blood

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BACKGROUND: Despite countless advancements in trauma care a survivability gap still exists in the prehospital setting. Military studies clearly identify hemorrhage as the leading cause of potentially survivable prehospital death. Shifting resuscitation from the hospital to the point of injury has shown great promise in decreasing mortality among the severely injured.

MATERIALS AND METHODS: Our regional trauma network (Southwest Texas Regional Advisory Council) developed and implemented a multiphased approach toward facilitating remote damage control resuscitation. This approach required placing low-titer O+ whole blood (LTO+ WB) at helicopter emergency medical service bases, transitioning hospital-based trauma resuscitation from component therapy to the use of whole blood, modifying select ground-based units to carry and administer whole blood at the scene of an accident, and altering the practices of our blood bank to support our new initiative. In addition, we had to provide information and training to an entire large urban emergency medical system regarding changes in policy.

RESULTS: Through a thorough, structured program we were able to successfully implement point-of-injury resuscitation with LTO+ WB. Preliminary evaluation of our first 25 patients has shown a marked decrease in mortality compared to our historic rate using component therapy or crystalloid solutions. Additionally, we have had zero transfusion reactions or seroconversions.

CONCLUSION: Transfusion at the scene within minutes of injury has the potential to save lives. As our utilization expands to our outlying network we expect to see a continued decrease in mortality among significantly injured trauma patients.

HEMORRHAGE AND WHOLE BLOOD

Countless advancements have been made in the past few decades regarding the care of the traumatically injured patient. However, despite those advancements, a vast survivability gap still exists in the prehospital setting. Delays in adequate resuscitation from the point of injury to the arrival at a definitive care facility have limited our ability to treat what may in fact be a salvageable patient. Military studies clearly identify that

ABBREVIATIONS: HEMS = helicopter emergency medical services; ISS = injury severity score; LTO+ WB = low-titer O D+ whole blood; MCI(s) = mass casualty incident(s); MOF(s) = medic officer(s); MTP = massive transfusion protocol; SAMMC = San Antonio Military Medical Center; STBC = South Texas Blood and Tissue Center; STRAC = South Texas Regional Advisory Council; UHS = University Hospital System.

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hemorrhage (extremity, junctional, and truncal) is the leading cause of potentially survivable prehospital death.[1] The ability to provide enhanced resuscitation capabilities at the point of injury using the tenets of remote damage control resuscitation has shown great promise in decreasing prehospital mortality among the severely injured.[2,3]

Historically, patients have had to wait until arrival at a hospital to begin blood component–based resuscitation. The current, most widely adopted practice is to administer blood components as follows: red blood cells (RBCs), fresh-frozen plasma, and platelets (PLTs) in a balanced ratio (1:1:1). An alternative modality, whole blood, can safely be administered to all ABO groups using cold-stored low-titer O D+ blood (LTO+ WB), which has proven benefits compared to component therapy and ABO group–specific approaches. The use of D+ product even in D– women of childbearing age is relatively safe compared to the risk of mortality with massive hemorrhage.[4] It is especially useful in emergency settings where multiunit or mass transfusion may otherwise be required.[5,6] In April 2018, the AABB officially changed their standards to include the use of whole blood for transfusion in specific situations as long as proper monitoring and volume restrictions are applied.[7,8] Hemostatic resuscitation, specifically using LTO+ WB, before arrival at a hospital provides a significant opportunity to improve prehospital care.[9]

When patients arrive at a hospital or trauma center in shock, the severity of their state of shock is sometimes too advanced to reverse; although transfusion may be started immediately upon arrival, that may prove to be far too late. The question that must be posed is how can these patients receive hemostatic resuscitation at the point of injury when they need it most—would it have been more beneficial to start the resuscitation with blood before arrival at the hospital? While this model does exist in a few settings, blood-based resuscitation, a key principle of remote damage control resuscitation, is currently not practiced in the majority of prehospital agencies.

SOUTHWEST TEXAS REGIONAL ADVISORY COUNCIL

To enhance collaboration among trauma care providers in the Southwest Texas regions, the South Texas Regional Advisory Council (STRAC), a 501(c)(3) designated by Texas statute to develop, implement, and provide trauma system oversight, uses an integrative, collaborative, and consensus-driven approach to develop and maintain a regional trauma system to decrease morbidity and mortality due to traumatic injury. STRAC, leading the nation's first multidisciplinary, multi-institutional, regional prehospital LTO+ WB program in rural, urban, and frontier Southwest Texas exemplifies this effort. The program capitalizes on an existing trauma system composed of helicopter emergency medical services (HEMS) capabilities and a pair of adult Level I trauma centers (one county-based and one military). The use of a four-phased systematic approach will be discussed. This systemic approach includes the placement of LTO+ WB at HEMS bases, ground EMS units, rural hospitals, and rapid accessibility from a regional blood bank for mass casualty incidents (MCIs). Figure 1 shows a map of the HEMS bases in the STRAC system.

Utilizing resources from the involved military medical center, testing protocols developed by the Army Blood Program for LTO+ WB[10] were adopted by the South Texas Blood and Tissue Center (STBTC). STBTC in turn established a donor recruitment program ("Brothers In Arms") to meet the sustainability requirements of a large regional LTO+ WB program.[11] We employed the use of nonleukoreduced, nonirradiated, male donor–only whole blood. It is defined as low titer using an anti-A/anti-B agglutinin titer level of 256. To sustain this program, roughly 22 donations are made per week; this has not led to any significant change in the amount of other blood products available in the region. Based on the demographics of South Texas we predicted that we would not have a sufficient population of D– donors to sustain the necessary quantities of whole blood. Because of this, we do not use D– whole blood in our current program. Women of childbearing age who are not suspected or confirmed to be pregnant are included in our program; it was decided that the risk/benefit ratio to patients favors the risk of antibody formation over the risk of death due to hemorrhage.[4] However, women with confirmed or suspected pregnancy are excluded from receiving whole blood at this time.

Prehospital and hospital health care providers were trained in the clinical nuances of administering LTO+ WB and logistic management of cold chain–stored products. Additionally, in an effort to minimize waste and maximize usage, a system for cycling older products from HEMS to the county-based Level I trauma center was established. We currently store our LTO+ WB for 35 days using CPDA1 anticoagulant—this is consistent with the practices of the Institute for Surgical Research and US Army Blood Program. It is stored in thermal isolation chamber system coolers carrying 2 units per cooler. The coolers were tested for temperature maintenance and were found to perform consistently with no unsafe elevations in blood temperature before exchanging the cooling core.

The blood on HEMS units is cycled off at scheduled intervals. After 14 days aboard HEMS units it is transferred to ground assets. At 28 days of storage it is then taken to the Level I trauma center for immediate use in trauma resuscitation. Should units not be used by Day 35 they are returned to STBTC and taken out of the donor pool. This method of cycling has led to the waste of fewer than 10 total units of product (out of just over 400 units collected) in the past 9 months. The expired units did not have RBC units recovered from them but were used by EMS for training and practicing field administration. At this time our

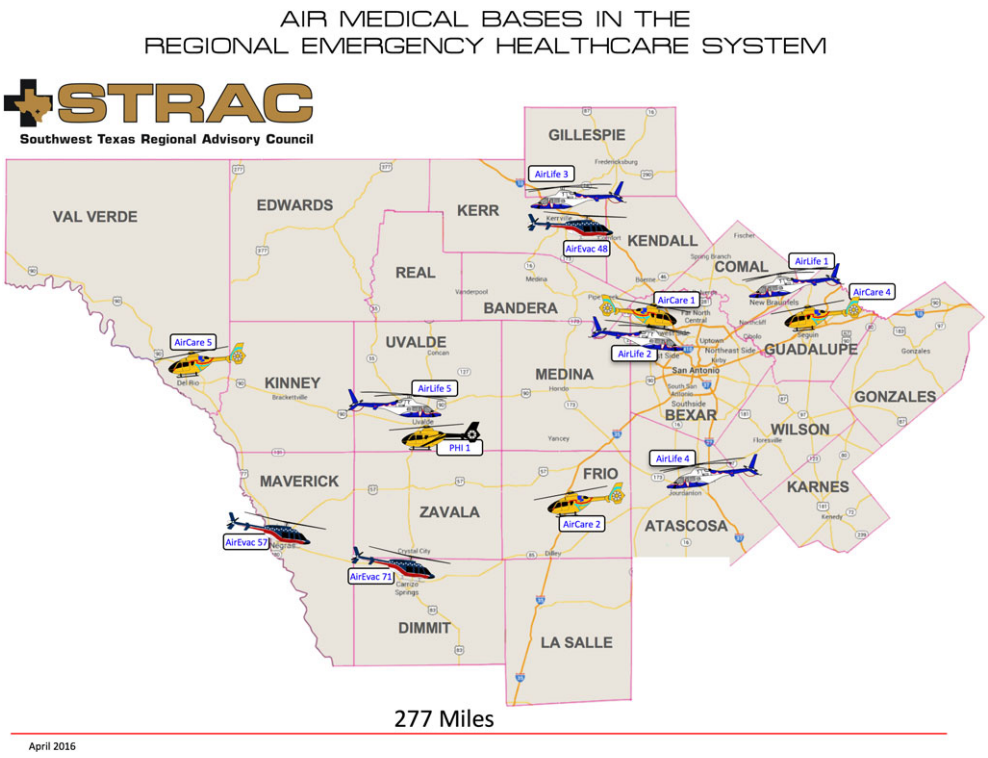

Fig. 1. Helicopter bases across South Texas. Participants include: Air Evac, Lifeteam, PHI, and San Antonio AirLife. Map courtesy of STRAC. [Color figure can be viewed at wileyonlinelibrary.com]

prehospital EMS and trauma teams are the only groups using whole blood although there are plans to expand into other medical and surgical specialties (transplant, cardiac, etc.), which will increase utilization as well.

A robust whole blood program requires the integration and collaboration of an interdisciplinary stakeholder team. This team must provide clinical and administrative education and proper cold chain management; they must also recruit sufficient numbers of donors to provide sustainability and ensure consistent product accessibility and utilization. Through the LTO+ WB program, STRAC was able to identify the necessary infrastructure needed to effectively expand into alternative prehospital platforms. This included obtaining/testing mobile coolers for ground units, trialing temperature monitoring devices to ensure quality, purchasing field-deployable rapid infusers with warming capability, supplying easily used blood tubing kits, and establishing replenishment sites after product use. This process improvement provided the ability to improve clinical outcomes for a larger population of trauma patients.

HISTORIC MORTALITY RATES WITH 1:1:1 MASSIVE TRANSFUSION PROTOCOL (A REVIEW OF OUR DATA)

Air transport offers emergency services the ability to strategically cover a large geographical area of responsibility. However, making LTO+ WB available to ground EMS may have a greater overall impact than solely relying on the HEMS platform. Recent analysis of our data identified that the preponderance of patients requiring emergency transfusion upon arrival to the trauma centers arrive by ground (EMS) transport. To compare the outcomes of LTO+ WB against traditional blood component therapy, we queried the trauma registries from University Hospital System (UHS) and the San Antonio Military Medical Center (SAMMC).

Our inquiry aimed to identify adult patients arriving between January 1, 2016, and August 31, 2017, at either Level I trauma center that required initiation of a massive transfusion protocol (MTP) upon arrival. In addition to patients who had a physician placed order for activation of MTP, we included all patients who received 10 or more units of blood products within 24 hours of arrival to the hospital. After identifying these patients, we performed a retrospective review of their demographics, injury patterns, and mortality rates. In the 20-month time frame the two hospitals received a combined total of 132 patients requiring activation of an MTP. A total of 109 of these patients arrived by ground EMS transport (83%) and 21 by air (16%). The mean injury severity score (ISS) of ground patients was 31 and the mean ISS of air patients was 28. Two patients were excluded from our mapping; one of these patients arrived by private vehicle and the other patient's transport

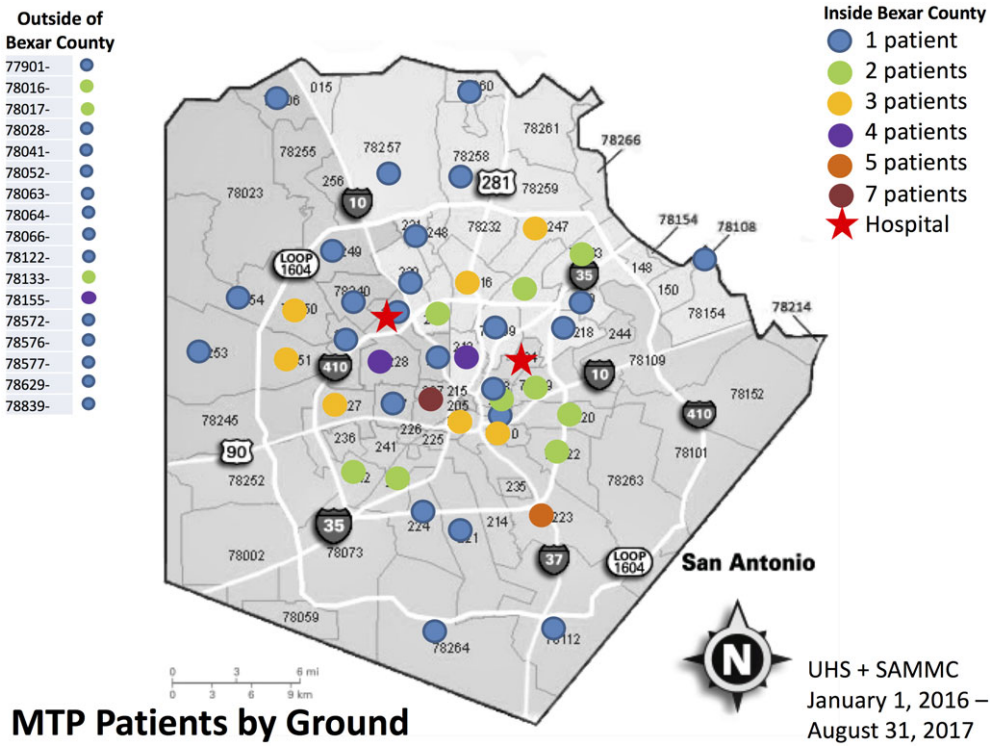

Fig. 2. Map of Bexar County showing density of MTP patients stratified by zip code arriving to UHS or SAMMC by ground EMS between January 1, 2016, and August 31, 2017. [Color figure can be viewed at wileyonlinelibrary.com]

method was not specified. Using this query, we then plotted a density zip code map of our county showing the location of patient incident and frequency of MTP patients transported by both ground (Figs. 2 and 3) and air (Fig. 4).

ADULT GROUND TRANSPORT

Mortality rate was calculated using all 109 patients. A total of 106 of the 109 patients were plotted in Fig. 2 to visually depict the frequency and location of patients requiring MTP. Zip code was unknown for the remaining three patients. Prehospital transport time was only available for 101 of these 109 patients and was thus calculated using those 101 values.

The overall mortality rate of our regional ground transport MTP patients was 63% (69/109; mean ISS, 31). These patients had a mean prehospital time of 30.8 minutes. Eighty-three of the 106 patients (78%) were transported from within Bexar County; the mortality rate of this subgroup was 66% (55/83) and the mean prehospital transport time was 28.8 minutes. Twenty-three of the 106 patients (22%) arrived from outside of Bexar County in the surrounding region. This group had a mortality rate of 61% (14/23) and a mean prehospital time of 43.9 minutes.

To determine the areas with highest frequency of severely injured patients requiring massive transfusion, we further separated out the high-density zip codes from lower-occurrence areas. Any area with four or more MTP patients arriving from a single zip code by ground ambulance was plotted on a new zip code map in Fig. 3.

A detailed look into this subset of high-density zip code data reveals a very similar mortality rate in this group at 63% (15/24; mean ISS, 31) with a mean prehospital time of 35.5 minutes. The data and patterns from Figs. 2 and 3 reveal that even with a relatively short prehospital transport time by ground EMS transport the mortality rate in these severely injured patients remains extremely high. From these data we infer that if hemostatic resuscitation were begun earlier, in the prehospital setting, there may be room to improve mortality rates.

ADULT AIR TRANSPORT

With the same process as for ground transport, a corresponding map was created for patients transported by air to both UHS and SAMMC (Fig. 4). Twenty-one of the 130 patients with a known mode of transport arrived by HEMS (16%). Twenty of the 21 patients are plotted in the figure; injury zip code information was unavailable for one patient. Mortality was evaluated using the data on all 21 patients. Prehospital transport time data was calculated for 16 of the 21 patients—the other five did not have available times. The results revealed an overall mortality rate of 57% (mean ISS, 28) with a mean prehospital time of 41.7 minutes.

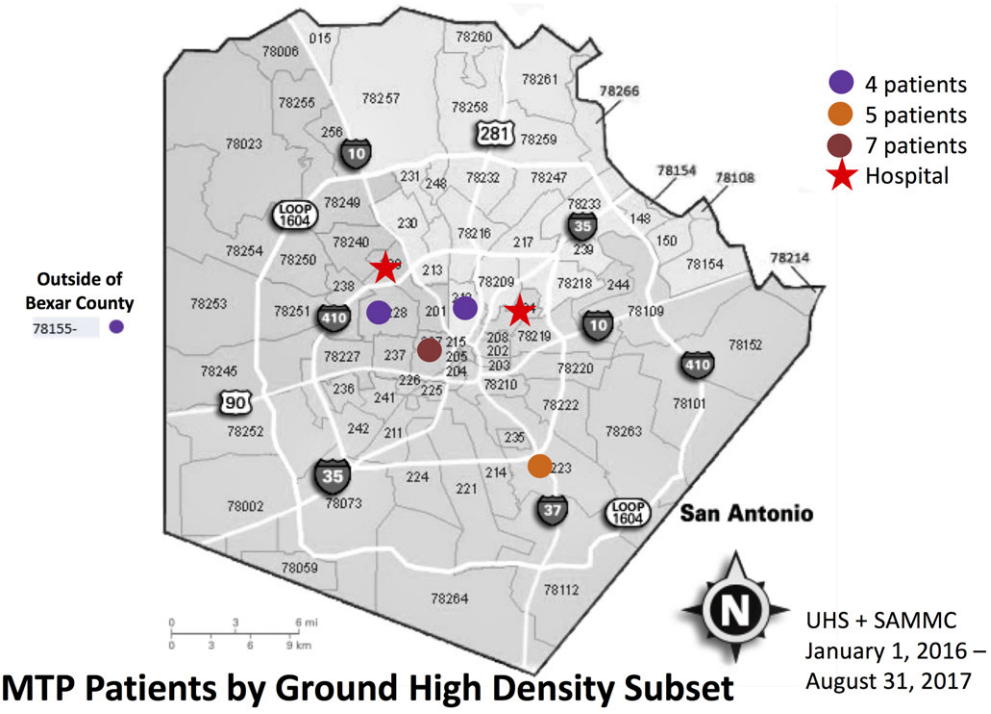

Fig. 3. Map of Bexar County showing zip codes with the highest density of MTP patients arriving to UHS or SAMMC by ground EMS between January 1, 2016, and August 31, 2017. [Color figure can be viewed at wileyonlinelibrary.com]

A majority (13/20 or 65%) of these patients arrived from within Bexar County. Their combined mortality rate was 62% (8/13) and the mean prehospital time was 41.8 minutes. From the surrounding region outside of Bexar County the mortality rate was 57% (4/7) with a mean prehospital time of 41.0 minutes. Once again, the data showed a relatively high mortality rate regardless of the fairly rapid transport times. Despite similar transport times (air a few minutes longer than ground) and similar ISS scores (28 air vs. 31 ground), air patient mortality rate was slightly lower than ground. This is thought to be due to the presence of more skilled providers with more advanced capabilities onboard HEMS units, which led to earlier initiation of specialty care.

PEDIATRIC PATIENTS

Pediatric trauma data were also examined for similar outcome measures. However, data were only available from UHS as this is the only Level I trauma center in the county caring for pediatric injuries. As MTP for pediatric patients is far less common we decided to query our registry for all pediatric trauma patients who received blood product transfusion within 24 hours of admission. This data encompassed a slightly larger time frame—January 1, 2015, to August 31, 2017. Within this 32-month period we identified 45 pediatric emergency transfusion patients who arrived at our hospital by ground. The overall mortality rate was 42% (19/45) and the mean prehospital time was 55.6 minutes (Fig. 5).

As with the adult population, a large proportion of the pediatric patients (69% or 31/45) arrived from within Bexar County. The mortality rate within this group was 35% (11/31; mean ISS, 27) and the mean prehospital time was 32.0 minutes. Outside of Bexar County, the mortality rate was 57% (8/14; mean ISS, 28), with a mean prehospital time of 108.0 minutes.

WHOLE BLOOD IN SOUTH TEXAS THUS FAR

From January 2018 when STRAC initiated their regional initiative to the time of this submission (6 months), 25 adult and five pediatric patients have received prehospital LTO+ WB. The majority of these patients (70%) were involved in a motor vehicle crash or motorcycle crash that met criteria for initiation of prehospital blood–based transfusion (Table 1). Nearly all of these accidents occurred on roadways greater than 60 miles from a Level I trauma center. At present, only basic data points including mechanism of injury, patient sex, and mortality outcome (initial hospital stay), which limits our ability to perform a true statistical analysis.

A cursory evaluation of our limited data demonstrated the following. Three of the 25 adult patients experienced non–trauma-related hemorrhage (one gastrointestinal bleed,

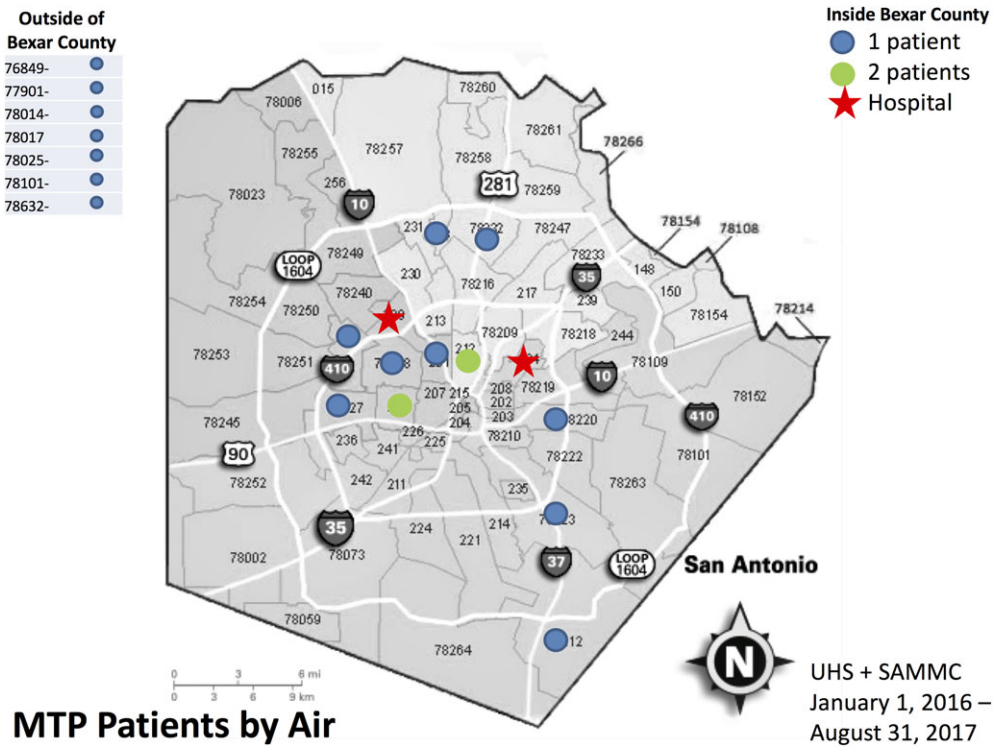

Fig. 4. Map of Bexar County showing density of MTP patients stratified by zip code arriving to UHS or SAMMC by air EMS between January 1, 2016, and August 31, 2017. [Color figure can be viewed at wileyonlinelibrary.com]

one complicated hemorrhagic cyst rupture, and one post-surgical bleeding) and 22 suffered traumatic injuries. All were sent from rural facilities to a higher level of care in San Antonio and received prehospital LTO+ WB in the helicopter. The overall mortality rate for adult patients who received prehospital LTO+ WB was 36% (mean ISS, 29). Nine of the 25 patients reviewed died before hospital or during that hospitalization; of those who died, more than half (five of nine) experienced a traumatic cardiac arrest on scene or while en route to the trauma center. The overall mortality rate for pediatric patients who received prehospital LTO+ WB was 20% (mean ISS, 29). The only death in that small group suffered blunt cardiac arrest on scene and after transfusion and aggressive trauma center resuscitation he was not able to be revived. The mean transport time within our region to the Level I trauma centers by air was 37 minutes. Zero of the patients thus far have shown any evidence of transfusion reaction after receiving LTO+ WB, regardless of D incompatibility.

FUTURE WORK (GROUND EMS AND RURAL HOSPITALS)

Analysis of the above figures and data shows a consistently high mortality rate associated with severely injured patients requiring MTP upon arrival to a trauma center. Hemostatic resuscitation, if begun early in the prehospital setting, provides the potential opportunity to decrease overall mortality rates. Our HEMS units were not previously administering prehospital blood products (unless started in a transferring facility) but are now capable of carrying LTO+ WB to the patient and beginning resuscitation upon their arrival on scene. Efforts are currently under way to have LTO+ WB readily available for the large, urban, ground EMS system and potentially for smaller, suburban and rural ground systems as well.

With the detailed mapping analysis above, specifically the high-density map (Fig. 3), Bexar County was examined closely to determine geographic locations where LTO+ WB on EMS units would be most beneficial—it would not be practical or feasible for all EMS units to carry this product. Fig. 6 displays a map provided by our regional EMS program outlining the estimated transit times from different areas of the city to the local trauma centers. EMS currently account for this information and track each transport time as part of their standard operating procedures. If these times extend because of traffic or construction, units are reassigned in real time to place more medics in an area that might be otherwise underserved or result in prolonged transport to the hospital.

To maximize utilization of LTO+ WB units and minimize waste, only a select group of EMS units will carry the product; this responsibility will fall to specialized paramedic

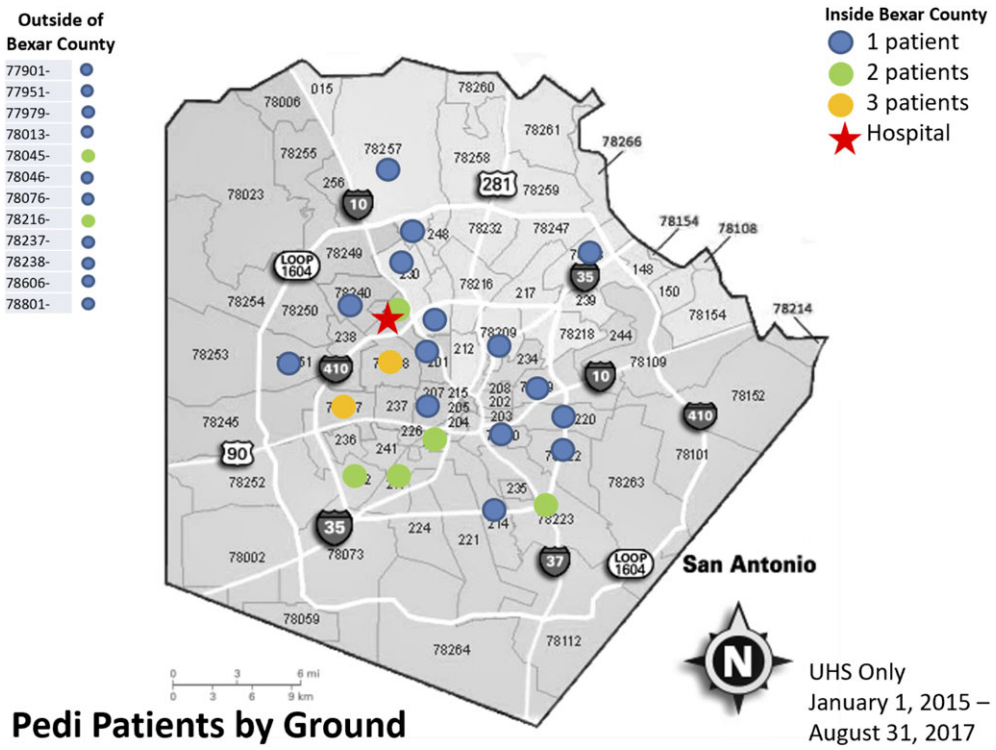

Fig. 5. Map of Bexar County showing numbers of pediatric patients that received emergency transfusion, stratified by zip code, arriving to UHS by ground EMS between January 1, 2015, and August 31, 2017. [Color figure can be viewed at wileyonlinelibrary.com]

officers known as medic officers (MOFs). MOFs are EMS lieutenants who have primary responsibility and oversight over roughly 10 EMS units in their geographic sector. They are responsible for the logistics, operational accountability, and supervision of paramedics on their assigned paramedic ambulances. These MOFs are available 24 hours per day, 7 days per week and can be dispatched to scene runs for the operational and logistic needs of their assigned crews. There are five MOFs in San Antonio, one in each of the four quadrants of the city with the fifth located within the downtown south central sector (Fig. 7).

TABLE 1. Transfusion criteria for prehospital use of LTO+ WB in our trauma network

Transfusion criteria (age > 5 years)	
Penetrating trauma (min 1 parameter)	Blunt trauma (min 2 parameters)
Physiologic parameters	
Systolic blood pressure (SBP) < 90 mmHg	
Heart rate (HR) > 120	
Shock index (SI) > 1	
Pulse pressure (PP) < 45	
Positive focused assessment with sonography in trauma (FAST)	
Point of care lactate > 5 mg/dL	
Known anticoagulant use or dual anti-PLT therapy	
Signs of hemorrhage (high suspicion of internal bleeding or visual evidence of external bleeding)	

Each MOF has a large Dodge dual-cab pickup truck response vehicle with advanced life support equipment and capabilities. The first MOFs to be trained and equipped with whole blood will be part of the police special weapons and tactics team. The nature of their job places them at high risk and they are often present at scenes involving major traumatic injuries. Next, we will supply each of the MOFs in sequence based on the MTP density mapping until all have been trained and outfitted with whole blood. The units servicing the areas with highest density MTP patients will be trained first and it will progress to those with lower density.

In addition to having to determine where to most effectively place these units, collaborative efforts have been made to understand the logistic challenges of cold chain storage and operator education. Further study is needed to better understand the impact of prehospital LTO+ WB usage from clinical and systems perspectives.

The addition of MOF units carrying LTO+ WB in San Antonio shows promise in the field of prehospital hemostatic resuscitation. However, it has a minimal effect on the additional need in the outlying rural and frontier regions outside of Bexar County. The final planned phase of our regional LTO+ WB project includes placement in rural facilities outside of Bexar County, Texas. A coordinated effort to roll out this program will proceed based on similar methodology to determine propensity and highest need once the MOF project is completed.

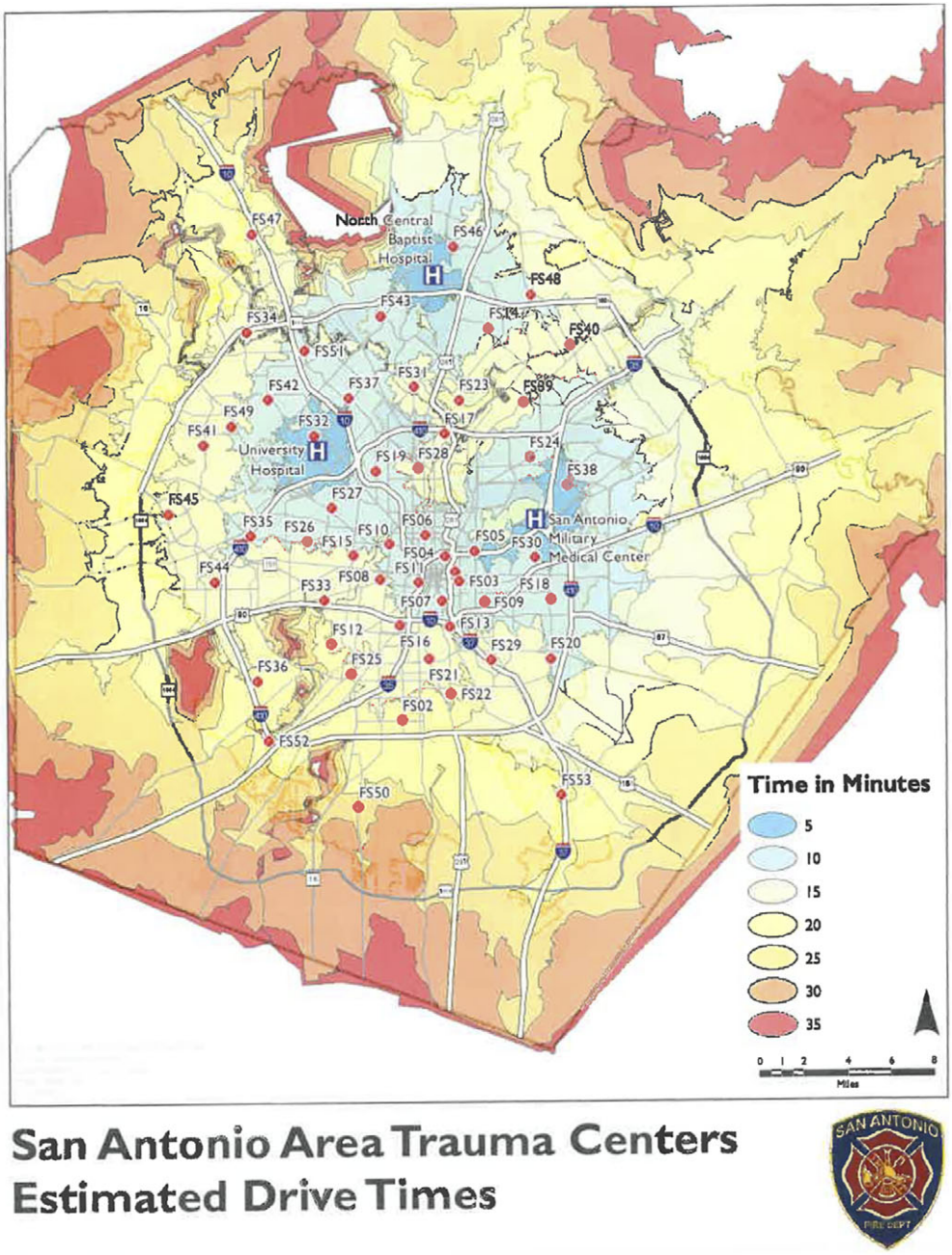

Fig. 6. EMS estimated drive times in San Antonio. [Color figure can be viewed at wileyonlinelibrary.com]

DEVELOPMENT OF MCI TRIAGE DECISION ANALYTICS

With an increase in incidence of mass casualty scenarios, the need for a proper response plan cannot be emphasized enough. Currently under development is a highly coordinated system to respond to mass casualty events such as the recent shooting at Sutherland Springs. This plan will effectively generate a multitier triage algorithm when resources to support casualty volume and acuity are insufficient. The application will project optimal utilization of critical resources such as aeromedical evacuation platforms, operating rooms, surgeons, blood, and so forth. In addition, the application will help to predict clinical futility in an effort to do the most good for the greatest number of casualties and minimize ethical dilemmas imposed upon prehospital providers. This proposal directly addresses concerns regarding rural mass casualty events. As discussed in a recent Assistant Secretary for Preparedness and Response (ASPR) Technical Resources, Assistance Center, and Information Exchange (TRACIE) report,

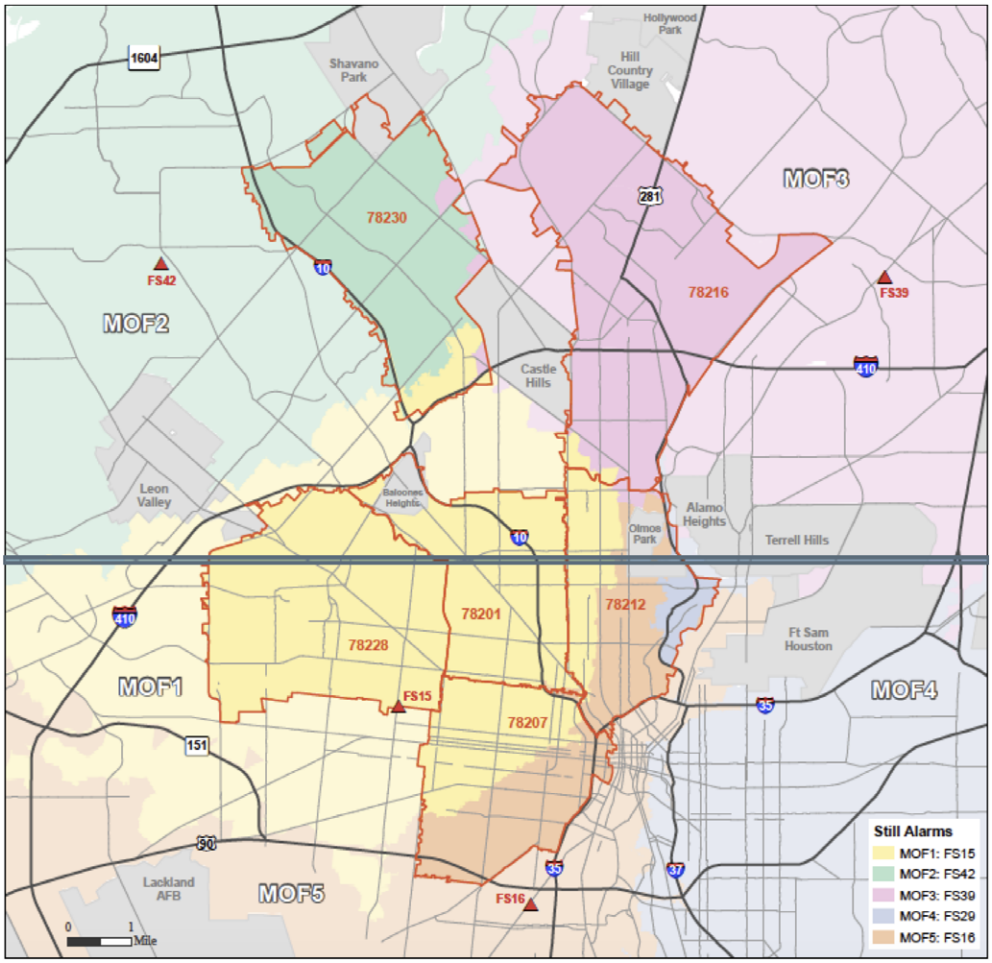

Fig. 7. MOF regions of San Antonio. [Color figure can be viewed at wileyonlinelibrary.com]

there is a need for collaboration between local EMS, surrounding communities, other hospitals, and EMS assets both by ground and by air.[12]

The current plan includes the following algorithm. After notification of a MCI, one of the MOFs will go directly to the STBTC to retrieve a high-capacity cooled container and 20 units of whole blood. To ensure that STBTC will be prepared, they have been included in the mass casualty alert system so as to be aware of the events in a timely fashion. Upon notification of an event, STBTC ensures that the blood is prepared for the designated MOF. If the MCI location can be driven to both rapidly and safely, the MOF will take the 20 units of whole blood and go directly to either the closest trauma center to the MCI location or to the MCI location itself. This choice of destination will be determined as the MOF approaches the scene and communicates with other first responders. Concurrent to this evolution, HEMS units equipped with 2 units of whole blood will be directed en masse to the scene. If the MCI location cannot be driven to both rapidly and safely, the MOF will instead take the 20 units of whole blood to an adjacent hospital and rendezvous with a helicopter on the helipad. The blood will then be flown to the MCI location.

The urgent need for a clearly defined system of care in response to mass casualty events was highlighted by a motor vehicle crash in Big Wells, Texas, on June 17, 2018. Fourteen people were involved in a high-speed police chase when they ran off of the road, rolling their sport utility vehicle. Multiple occupants were ejected from the vehicle and initial assessment on scene noted four dead with 10 others injured. The scene of the incident was located more than 100 miles from the nearest level one trauma center.

Nine HEMS units in our regional trauma center were directed to the scene to care for and transport the injured patients. A total of six patients were transported to one Level I trauma center; one died upon arrival. Four more patients were taken to the other Level I trauma center, which is also a pediatric Level I center for their care. Of note, three patients received prehospital LTO+ WB. Two of these patients each received 1 unit of LTO+ WB and were transfused while during transport from scene (one patient died), and one was transfused 2 units during an interfacility transfer between

hospitals (this patient survived). Additionally, a fourth patient met criteria for LTO+ WB transfusion during transfer but that particular HEMS unit was not yet carrying the product. To our knowledge, this is the first time that whole blood has been used in the civilian prehospital setting in a MCI.

CONCLUSION

Despite the best efforts to effect change in prehospital care of traumatically injured patients, only a handful of interventions (tourniquets, pleural decompression, thoracostomy, etc.) have proven to make a drastic difference. Rapid arrival of ground EMS units, support from HEMS units with skilled, specialized providers and immediate transport to the hospital or trauma center setting have decreased mortality rates but those rates are still significant among the most severely injured. The STRAC recently implemented a plan of action including administration of whole blood at point of injury that shows great promise in lowering the aforementioned mortality rate.

Initial placement of cold-stored LTO+ WB on helicopters was a substantial improvement in our trauma system. However, as our data show, the proportion of patients that would benefit from whole blood largely lies in favor of those transported by ground units within Bexar County. To effect the greatest change, a process was devised to make LTO+ WB available not only in the field for significant traumas but also on site for MCIs. A thorough, detailed plan to coordinate asset mobilization and use is key to making the process possible. Experienced providers such as our MOFs will make rollout a much easier transition and help to manage logistic issues as they arise. In addition, systemwide analysis via regional performance improvement activity within STRAC will provide helpful oversight in ensuring the plan can be altered to fit each situation. As evidenced by our recent experience in Big Wells, Texas, in June 2018, the use of LTO+ WB not only during helicopter transfer to the trauma center but also at the scene of the incident is now a reality.

A review of the preliminary data from our trauma centers and HEMS units indicates a potential for reducing mortality when LTOWB is used prehospital for patients with significant traumatic hemorrhage. While the data are underpowered and insufficient to draw any true conclusions, the fundamental concept is sound—bleeding patients need blood replaced as soon as possible. Transfusion at the scene within minutes of injury has the potential to save lives.[3] As our utilization expands to our urban, suburban, and rural EMS systems as well as our outlying network hospitals, we expect to see a continued decrease in overall mortality among our significantly injured trauma patients. It is plausible that patients who would have died before this prehospital transfusion program will now make it to the trauma center alive, only to die subsequently. This would potentially raise the death rate in the trauma center. Only time and further study of outcomes will provide that answer. For more information regarding our program please visit www.strac.org/blood.[11]

CONFLICT OF INTEREST

The authors have disclosed no conflicts of interest.

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