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What we do matters

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SUMMARY

Amidst all the bad news and divisiveness we are surrounded with every day, there are many reminders from our field that highlight that the things we do really do matter. The scope of this talk focuses on blood, but it is important to remember that the concepts discussed can be applied to all aspects of medical care. Level III evidence

INTRODUCTION (SLIDES 1–5)

The title of the talk is 'What we do matters', and I hope that everybody in here really feels like they are part of this incredible team and that what we all do matters. Karen Doyle talked today about being a candy striper (hospital volunteer). I was a candy striper, and that was my first step into the hospital. Then, I was an OR Tech passing instruments to the surgeons, some of them nice guys, some not so nice guys, but I learned that it was the team that matters. I am going to talk a lot about blood, but I want you to substitute whatever it is you do because what we do matters to improve the quality and outcome of the patient. (online supplemental file 1).

I am honored to give this lecture. I went and read about Dr. Wolferth, for whom they named the lecture. I did not know him and never met him. When you read about him, the thing that stands out is that everybody said he was a 'surgeon's surgeon', and that is a great compliment from one surgeon to another. He worked to establish the Pennsylvania trauma system, which is a model around the country and established this meeting.

I like telling stories to illustrate points. I'm going to weave together several different themes that you will have to follow. I will touch on historical experiences, research policy, training, and worldwide impact and will move through them quickly. Remember, it is not just about whole blood. Blood is just an exemplar of what we do. There is some back and forth and more than a little bit of military emphasis in this talk. What we do matters; please remember that. I grew up in the South as a Southern Baptist. I am not going to preach to you, but what we do matters. I am going to hit that theme repeatedly as we go through this data.

HISTORY (SLIDES 6–17)

History is important. Young people do not care about history, but old folks do. I did not know history when I was a surgery resident and young faculty, but the older I get the more I appreciate medical history, especially military medical history and the lessons we need to retain. Sam Carmichael is a young faculty surgeon at Wake Forest and wrote this beautiful paper discussing the history of blood. The first transfusion that we can find was in 1667, given for mental illness between a married couple.¹ It did not work out very well, and thus, the therapeutic potential was considered limited. It was made illegal to give a blood transfusion for a while by the church; therefore, nothing much happened for quite some time. Wars, including the Spanish-American War, the US Civil War, and then World War I led to blood transfusion going 'gangbusters'.

I am skipping forward to World War II now and Edward 'Pete' Churchill wrote about what he did on the battlefield driving around in a jeep. This is a great book if you can find it, it is currently out of print (Surgeon to Soldiers). One of the stories in this book describes how the US military went to war with plasma and crystalloid in World War II.² It was not felt to be necessary to have whole blood and there were no components at that time. The British were using whole blood because they had not forgotten the lessons from World War I. On review by COL Churchill, their patients were doing better than ours. Our patients were dying pale, and their patients were living. So, he started writing memos and some of the generals ignored the memos from the colonels; they still often do that today! What he did, at great personal and professional risk, was go to the press. There was a roving New York Times reporter, and this is the article that was published showing that patients with whole blood transfusions did better.3 This was published in the New York Times, and guess what happened? Six weeks later whole blood was available to US casualties on the battlefield. A pretty amazing story about the power of the press, public relations, and military guys going outside the chain of command. Who would ever imagine a military guy would do that? Going to the press to accomplish the mission to save casualties and improve the quality of care.

This paper was published in Annals of Surgery documenting probably one of the most important lessons learned in World War II.⁴ These are pictures of medics on the battlefield giving dried plasma to patients. They had whole blood back in the hospital where doctors were available, but these were medics giving dried plasma in World War II, and hopefully, we will see this again in the next couple of years in the USA. Then, you move forward to the mid-60s, and Shires and Carrico became famous for writing about crystalloid. History is not only important to teach us what went right but also what went wrong. They were presenting their data in Galveston the day Kennedy was shot in Dallas. They were from Southwestern, but since they were down in Galveston presenting papers about crystalloid, they were not available to take care of their president. They talked about 4-5 L being the right amount of fluid.5 Because of Carrico and Shires and

their influence on patient care, crystalloid became the dominant resuscitation fluid, whole blood went away, and components were secondary. When I was a surgery intern in 1985, we would routinely give 10, 20, and 30 L of crystalloid to patients with trauma. Some of the folks who have gray hair in the room remember that and are nodding their heads. Pretty amazing when compared with what we do today.

At the same time ARDS, otherwise called 'Da Nang lung' in Vietnam, started to be widely described. There were correlations with crystalloid but not causality because the studies were not randomized. It was rarely described in World War II, and the clinicians were just as smart as us. They were giving whole blood and did not describe ARDS or 'Da Nang lung' or the problems with respiratory failure that were described in Vietnam. This next paper has already been mentioned discussing supranormal resuscitation. When I was a fourth-year surgery resident, I worked in Shoemaker's and Fleming's labs at Martin Luther King Hospital in Los Angeles. I put in Swans in the Emergency Department, measured cardiac index, and drove patients to get their cardiac index into supranormal ranges giving 20 or 30 L of crystalloid. I participated in that. It is pretty amazing that 10–13 L of crystalloid is what we routinely gave back then.⁶ Dr. Zsolt Balogh, who worked for Fred Moore at UT Houston, published this paper, which was one of the more important papers during that time which said that lots of crystalloid was not good.⁷ We frequently saw patients with abdominal compartment syndrome with no intraabdominal injury. I have not seen one of those presentations in years. Everybody knew how to measure bladder pressures; we knew to open their abdomen in the ICU because we gave too much crystalloid. That was an iatrogenic resuscitation injury that we created by giving excessive crystalloid. Animal research using controlled hemorrhage models and misunderstanding how to use crystalloid clinically led to these problems. Not only do you have to know history, but also you have to understand the experimental models and read the methods section. Not understanding these issues absolutely led to increased death, morbidity, and mortality.

If you look at this evolution of resuscitation from whole blood in the Civil War in the USA, the first transfusion I can find was in the Civil War given to a young southern man whose surgeon ended up being the Chair of Surgery and Dean at the University of Arkansas where I went to medical school. The guy who donated the blood was a healthy German; it is documented in the paper. For 126 of the last 159 years, blood has been the primary resuscitation product. If you look at history, we got confused in the 70s, 80s, and early 90s and have come back and have seen, now in a data-driven fashion, the error of our ways. It is important to understand the evolution of resuscitation. They are not always right, and those people who write guidelines are not always right. You need to know why it happens, know the methods and models, and understand the science. What we do matters here. What we do as a group sometimes hurts patients, sometimes it helps, but we always need to track patient outcomes.

EXPERIENCE (SLIDES 18–24)

My next experience came as I joined the Army. I did not have the money to pay for medical school and got an Army scholarship. The Army sent me to El Paso, Texas for surgery training, and that was great. My buddy called up after I finished training and said that they had a job for me at Fort Bragg, North Carolina working with Special Operations. I then deployed all over the world with the Joint Special Operations Command for a decade. If I could still do it, I would. It was an amazing opportunity to

go around the world with the best soldiers, sailors, airmen, and marines in the world; an incredible experience. The first unit of whole blood I gave was in 1993 in Somalia, and I thought we were going to go to jail. Nobody gave whole blood in 1993, and nobody talked about it. We wrote about this a while later. If you notice these papers, it took us 7-10 years to write after 1993.89 I was not writing papers in 1993; I was trying to do hernias, gallbladders, and operate on everything. In 1993, an anesthesiologist named COL Denver Perkins who had been an infantry officer in Vietnam in the midst of the events in Somalia, came to us and said, "Let's do a whole blood drive." I had never heard of it. In my military and surgical training, nobody ever mentioned doing a whole blood drive or walking blood bank not once. I seriously thought we were going to go to jail. We thought Denver was kind of crazy, but he was a great doctor and somehow he knew about whole blood. Soldiers lived because of Denver Perkins. One-third of the hospital donated amid the mass casualty event; one-third of the hospital laid down, gave blood, got back up, and went back to work. Thirty-six straight hours of continuous hospital operations, nobody took a break; talk about commitment and dedication. It was pretty amazing, and Denver Perkins made that happen.

After this, there were a lot of papers discussing how and when to use blood. Hundreds of other papers were released from single and multicenter retrospective studies from around the world. At the same time CAPT Frank Butler, a good friend of mine, a Navy SEAL, and ophthalmologist started looking at what we were doing in trauma care. He looked at combat casualty care with fresh eyes and essentially said that it does not make sense. It is amazing to have an ophthalmologist look at what we do as a group with an objective viewpoint. Frank is the author and father of tactical combat casualty care, TC3. In the civilian world, TC3 has developed into tactical emergency medical services (EMS) and in the military, it has become the standard around the world. The Joint Trauma System (JTS) wrote a guideline in 2004 about whole blood and products and has updated that guideline about every 2 to 3 years.¹⁰ In 2014, Frank and I wrote a guideline paper that said whole blood should be the primary resuscitation fluid prehospital.¹¹ Jeremy Canon followed that up in 2017 with a civilian guideline paper and talked about 1:1:1 (blood, plasma, platelets) component resuscitation as we sought to recreate whole blood in the hospital and to be a civilian standard of care.¹² The last guideline update was in 2019 and discussed damage control resuscitation; resuscitating those patients who are bleeding hard. These guidelines refer to the 10% or so that are bleeding and resuscitating them in a different way than you would the hemodynamically stable patients.¹⁰

From a military point of view, experience on the battlefield is critical, there is no substitute. When the military is back in garrison, personnel are doing civilian care but going down range is very different. Leaders must deploy and take care of patients down range whether it be surgical or non-surgical; it does not matter. That environment is different, and it changes the way you look at the world from a medical point of view. You learn the problems on the battlefield and come back to work on the problems. You solve the problems, implement solutions, and keep that cycle going repeatedly. It is a unique experience that makes military medicine different.

Military medicine in the rear area, whether you are in a civilian or military hospital is no different than being at a civilian center. The difference is delivering deployed care and that is what makes it unique. I would say the same thing on the civilian side as well. To effectively lead, whether a nurse, a candy striper, an OR tech, or a surgeon, you must take care of patients. You do

not have to do it full time, but you have to keep your hands in the game and take care of patients so you can know the problems in research, policy, etc. Study the problems in the lab, the boardroom, or wherever the environment may be, then implement the potential solutions and iteratively study them through your data-collecting processes.

RESEARCH (SLIDES 25–34)

When I was a surgery resident in El Paso, Texas, I did zero research and published one paper on acalculous cholecystitis. I got more involved with research after a soldier bled to death in my hands in Somalia. It got me thinking about bleeding and hemorrhage control. Moving forward 15 years, I found myself leading a research center at Brooks Army Medical Center in San Antonio, Texas, where I had the opportunity to work with groups and teams of people who were much smarter than I and knew more about animal models and study design. I had been on the battlefield, and I knew the major problem was potentially preventable death from bleeding. We focused our efforts. When you get to be a colonel in the Army during a war, it is important to stay focused on the problem and deliver solutions. We needed a focused direction and program of research.

Jill Sondeen, Mike Dubick, Charlie Wade, and Bijan Kheirabadi focused their efforts for years on better ways to stop bleeding and improve resuscitation.¹³ They were successful. I think it is also important to say where we could have done better. We did a lot of animal studies, but we did zero human studies. It was a horrible mistake. Animal studies are important, preclinical studies are important, and I am not disparaging that at all. But, we should have done more human studies because that is what moves the needle. This is a little diagram (slide 28) that demonstrates the cycle that I have talked about: deploy, take care of patients, and figure out what the problems are.¹⁴ Sort out the big problems and take them to the lab, not the little ones because you cannot work and solve everything. The lab today can be a computer, cell culture, whatever you want and need it to be. Figure out a potential solution, implement it with a good methodology, study the results, and then complete that cycle. What we do matters no matter where you work, whether it is in simulation, prevention of hemorrhage, or pain control; all the things we do here need to be optimized. Imagine improving the outcome in each one of those sectors by 2%. What would that mean at the end? It would be phenomenal, but we as a field of study do not programmatically do research working in all these different areas.

What do most funders fund-they fund preclinical work. What does the National Institutes of Health (NIH) largely fund? They fund preclinical and basic science research, and I have done that. I have submitted and been awarded those grants. It is cool to do cell culture, but it is cooler to implement those findings in patients and see them improve. What should they fund? I think they should fund more clinical work and rebalance this thing a little bit so we can improve clinical outcomes. The real bloody vicious cycle is that we have traditionally done suboptimal clinical care. The guidelines are almost all expert opinion and a lot of times when you finally do the studies, you discover they were wrong, just like the crystalloid data. We have a lack of consistent federal funding to support high-quality clinical research and that funding is not commiserate with a societal impact. Middle ear infections are funded at a higher rate by the NIH than bleeding to death in patients with trauma. That is a horrific fact. Few investigators research injury; why is that? Few investigators are doing injury research because the funders largely do not fund

clinical injury research like they do middle ear infections. Ultimately, you have to put bacon on the table so you can eat and support your kids (and lab). Because of that, we lack high-quality data in most of the things we do, and then we have to rely on expert opinion. Our expert opinions and low-quality data get published in lower quality journals, rarely the New England Journal of Medicine (NEJM). It is really rare, almost unheard of, to see a trauma paper published in the NEJM or Journal of the American Medical Association and that yields low-quality care. This funding issue is really important, this is the real bloody vicious cycle (slide 31).

There are some shining research examples here such as COL Stacy Shackleford who put together transfusion data from the battlefield. This is observational data, not prospective and randomized, but the statistics and the methodology are about as good as you can get. She demonstrated a huge outcome difference by giving blood products early in the prehospital setting. Outcome data with blood products given prehospital was the nail in the coffin for prehospital crystalloid for the military. The outcomes over 30 days showed huge differences in survival.¹⁵ A paper that I think is the most important trauma paper, maybe ever, certainly in the last decade, is this paper by Jason Sperry published in the NEJM showing a 10% absolute difference in outcomes over 30 days by giving red blood cells (RBCs) and plasma prehospital versus crystalloid.¹⁶ This was a prospective and randomized multicenter study published in the NEJM. There is nothing that I am aware of that has the impact of this study. If you are not doing prehospital blood products, you are wrong. If you are not doing it, it is because you have not tried hard enough to get prehospital blood products. It is not easy, and you cannot currently bill for it. It is difficult, but this paper is compelling. What Jason and his team did matters dramatically. There are people in the room who are fighting to get blood products in your region and that effort matters.

There are now hundreds of non-randomized studies with whole blood and two prospective randomized studies are coming down the pike.^{17 18} Trauma Resuscitation with Low-titer Group O Whole Blood or Products is one of them; it is an in-hospital study and LITES-TOWAR is a prehospital study. The federal government is starting to get on board funding high-quality clinical studies. These two studies are starting and enrolling right now. We will have some results from these in the next 3 to 5 years. Finally, from a department of defense (DOD) point of view, it is important to deploy research teams to the battlefield. For the military audience, this is critically important. You cannot get better unless you collect data and do research and you have to go where the action is happening.

DISSEMINATION, IMPLEMENTATION AND POLICY (SLIDES 35–43)

I am the worst guy in the world on policy, it is not my forte at all, but I know it is really important. You can do all this work in the front, but you must back it up with paperwork, the systems, and all those things that happen behind the scenes. The JTS was first described in 2003, and while research was part of the JTS at the beginning, today it currently does not have a research arm. But, COL Jennifer Gurny is fixing that. Hopefully, in another 6 months, we will be able to put the research arm next to the performance improvement registry and operations so there will be a comprehensive military trauma system. Whole blood was the first JTS clinical practice guideline that was described in 2004 and has been the recommended fluid of choice in the military; civilian adoption is coming. The military blood community has written more about this as opposed to some of the other blood communities in the USA. The military is fully on board with providing whole blood as far forward as possible.¹⁹ Medics are carrying whole blood in their rucksacks down range and transfusing while wearing night vision goggles so that in the middle of the night, in the middle of a firefight, whole blood can be given. If the military can do that, we can do it in the civilian world with paramedics, do it safely, and keep track of all the paperwork. We have heard already about the experience down in San Antonio. It is this unique environment where they created a comprehensive system for blood. Level 4 trauma centers have whole blood available in the ED. It is on ground ambulances. It is on helicopter ambulances, and it is, of course, in the level 1 and level 2 centers. They have hundreds of units of whole blood moving around that region at all times. Cross-leveling between centers enables them to rapidly move units in the case of a mass casualty event.²⁰ Hazelton's paper was discussed this morning and is the second-best paper, in my opinion, of the prospective randomized papers coming down the pike. Presented to the American Surgical Association and published in the Annals of Surgery, they presented a large number of patients who received whole blood versus components. The whole blood patients did dramatically better. They were sicker, got whole blood, and yet had dramatically improved outcomes compared with the component group.²¹

Whole blood pre-hospital and in the hospital has yielded better clinical outcomes. The DOD guideline says whole blood is standard, and CAPT Butler wrote in 2014 that whole blood prehospital and in the hospital is the way to go.^{22 23} This is important for those of you not in the military; this is the official policy. Note that it was published in 2022 after two decades of war. After whole blood was used repeatedly for almost 20 years, the Assistant Secretary of Defense for Health Affairs published this policy guideline which made it official. What about across US civilian trauma centers? This is data from the Trauma Quality Improvement Program (TQIP) and the National Emergency Medical Services Information System (NEMSIS). TQIP is an in-hospital quality data while NEMSIS is pre-hospital.²⁴ There is a major problem with those two databases - they do not talk to each other, and it is a fatal problem. You cannot see what you do in the civilian pre-hospital setting and how that affects what happens in the hospital. We need to have a smart person fix that. I am not capable of doing it, but it needs to be fixed. People are working on it, and it might be solved soon.

Over the last five or six years the number of centers that have whole blood available in the civilian world at trauma centers and that submit data to TQIP has increased. It is a subset that has increased pretty dramatically from 16% to 24%. We recently updated the data. It is not published yet, but utilization is up to 50% in the hospital. The NEMSIS results remain pretty low; the data from a couple of years ago, only 0.5% of eligible patients who were submitted to NEMSIS had received blood products pre-hospital.²⁴ There is a great disparity there, and why is that? I think this comes down to policy. Civilian EMS agencies have logistics issues, but logistics are solvable once you decide to do it. There are 150 EMS agencies around the country with whole blood out of 5000 plus agencies. While 150 sounds big, it is minuscule. You cannot bill for prehospital blood in the United States. In our system, if you cannot bill for something, it does not go far. Think about the NEJM paper. The biggest impact ever of any intervention that I am aware of, and you guys can correct me, but a 10% absolute difference in 30-day survival, prospective, multicenter, and randomized data is significant. I do not know of anything like that, and yet we cannot distribute

blood products across the entire United States largely because EMS agencies cannot bill for it. That is publicly stupid. What we do matters, and we all need to coalesce around this issue and inform the policymakers how publicly stupid that is.^{25 26} The JTS clinical practice guidelines are for the military but are not fully implemented across the military healthcare system. There are about 60 guidelines describing the lessons learned on the battlefield, but they are not fully implemented at all military trauma facilities (MTFs). There are major MTFs that have not implemented the lessons learned from the war, and that is a problem.

TRAINING (SLIDES 44–49)

The military is good at training people. These military-civilian partnerships, which you have here in Maryland and other locations, have existed for a long, long time and are critically important to training.^{27 28} From a whole-blood point of view, I like to put it in terms of 'what if' it were my kids/your son or daughter. My kids are 20 and 22 and if they were to go down range and are injured, I want the medic, the doctor, and the nurse that are taking care of my son or daughter, or your son or daughter to have transfused whole blood before arriving on the battlefield. Where is that going to happen? Here in the civilian world. The military nurses, medics, and docs need to have seen prehospital and hospital transfusions before they hit the battlefield and take care of our sons and daughters. That is what this talk is about, and yet that is not really happening. There are 52 MTFs, yet today only nine have whole blood. The policy you saw earlier says whole blood is the standard on the battlefield, but it is not the standard in military hospitals; kind of crazy. In these military-civilian places, there are at least 87 large militarycivilian collaborations around the country; how many of them have whole blood-it is unknown. It is not a data point that is collected. Of the level 1 and 2 trauma centers that report to TQIP, about 50% have whole blood in the hospital; whereas, whole blood pre-hospital in this military-civilian collaboration is still unknown. The military clinicians, when they come to your civilian center, need to learn the things they will do down range, and whole blood is most important.

Training such as Stop the Bleed is important. May is Stop the Bleed month so I could not have this talk without briefly talking about it. It is important to do the outreach training and translate the lessons learned from the battlefield. One of the things we learned on the battlefield was putting tourniquets on in the hospital, and it seemed to work pretty well. Then, we put tourniquets in the hands of the medics, and that was good but what made significant improvements was when we put tourniquets in the hands of every soldier. This progression was data driven and published. In a similar fashion in the civilian world, tourniquets went to the ED first, then to medics, then to police officers, and now we are training non-medical civilians to apply tourniquets and stop bleeding. We talked about whole blood, and if you combine Stop the Bleed with blood donor centers and increased donations, it is a powerful combination. We need to train as closely to how we fight. Again, military phraseology describes currency in all aspects of trauma care as critical and taking the systems, registry, research, clinical care policy and guidelines back up to the C-Suite to do the things that we need to do.

WORLDWIDE IMPACT (SLIDES 50-60)

This is a research agenda from international folks around the world talking about whole blood. It is there on a worldwide trauma agenda.²⁹ The UK is now studying whole blood (Study of Whole Blood in Frontline Trauma 'SWIFT'), and now they

are, in some respects, pushing forward from where we are with the blood product transfusion policy.³⁰ The French have been pushing the envelope with dried plasma for many years. They did not give up dried plasma after World War II, they kept it in production for their military. They are now producing dried plasma, using it, and studying it for use in civilian EMS. They are also now doing a whole blood study (Sang Total pour la Reanimation des Hemorragies Massives 'STORHM').³¹ I had the opportunity to go to the LVIV hospital in Ukraine a couple of times last year with The Global Surgical And Medical Support Group (GSMSG). Whole blood was illegal in April of 2022, but after we talked about whole blood, tranexamic acid, 1:1:1 transfusion, and a walking blood bank, changes were instituted in July 2022. Within 3 months, the Ministry of Health published an entirely new policy stating that they legalized and implemented many aspects of the ITS's clinical practice guidelines to include pre-hospital and in-hospital whole blood. Pretty amazing what a war will stimulate you to do from a rapid change point of view. I have the opportunity to speak to Ukrainian medics and doctors in 3 days, and we are going to talk about prehospital whole blood and the walking blood bank. I am pretty excited about that. Many folks are using whole blood; again, it is just an example of what we do that matters. Whole blood is just an example of what we all do. It is being used for postpartum and GI bleeding, another example of innovations from war moving into the civilian space. On PubMed, the articles about whole blood have exploded, and there are now thousands of papers talking about this.

CONCLUSIONS

In summary, in 1993, we used whole blood, and I thought we were going to go to jail. Today, whole blood has become the standard around the world and not just for patients with trauma. We need to have a DOD and NIH-funded clinical research program that seriously studies one intervention after the other, not just whole blood, but many of the others we talked about this morning. What we do really does matter. Sometimes at 2 a.m., when you are taking care of the 100th patient, that is a little bit hard to remember. It is our entire group, including the administrators, the janitors, the candy stripers, and everybody on that team that really matters. We cannot do our work without that team, and that is personally what I like about what we do; it is the big team, whether it is clinical care or research. It is fun to challenge dogma and swing at windmills a bit. Do it respectfully, do it with data, and do not give up. It is the way we make progress. During a war, the military moves quickly, at the end of a war, the military moves slowly, and in between wars, it does not move at all. In fact, it often moves backward. Where are we now-we are in between wars. Casualty flow is still happening, but thankfully, it is at a low level. So, who is going to drive innovation in the interim period—it is the civilians. That is where the trauma patients are and where continued innovation is going to happen. The military must be ready for the next war. The civilians will be the repository of the hard-won lessons learned on the battlefield and the innovation that occurs in between wars. What we do matters. The stories go on and on, and I just ask for you to stop for a minute and be proud of what you do.

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