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MEMORANDUM

Qualified for Public Release

TO: Team AmbuStat
FROM: Jason Thompson
DATE: January 16, 2016
RE: Why AmbuStat?

The intent of this memorandum is to address the question that is being posed numerous times every day and that is 'Why AmbuStat?' We have intended to take time to intimately document the history of the program, so I am going to use this opportunity to do that and, hopefully, before you reach the end, you will discover the answer to that question.

In the latter part of 2014, during the Ebola Virus outbreak, we stumbled upon an opportunity to investigate the ability of prehospital care providers to manage the outbreak. This led us to conduct polls with our colleagues and customers with the goal of gaining an appreciation for the challenges that were being faced. It did not take long to realize that most of those polled were either confused or scared about the virus and their ability to deal with it. As we digested what we were hearing, we realized that there was a common denominator among all of them and that is the general lack of familiarity with proper infection prevention and control practices and a fundamental misunderstanding of the term 'decontamination.'

Didn't we figure this all out after the global HIV/AIDS epidemic? Didn't we develop standard precautions and don't those precautions deal with infection prevention and control? If so, why the lack of familiarity? Yes, standard precautions were adopted in 1996; however, we believe that the focus of the precautions are too narrow as they deal with the transmission of blood borne pathogens, rather than pathogens, altogether. What is a pathogen? A pathogen is an infectious biological microorganism that causes disease or illness to its host, such as viruses, bacteria, protozoa and fungi. What is a blood borne pathogen? A blood borne pathogen is a pathogen that can be transmitted through contact with contaminated blood and body fluids, such as semen, vaginal secretions, cerebrospinal fluid (associated with the brain and spine), synovial fluid (associated with the joints), pleural fluid (associated with the lungs), peritoneal fluid (associated with the abdomen), pericardial fluid (associated with the heart) and amniotic fluid (associated with pregnancy). The focus is on blood and those body fluids since they have direct correlations to three diseases, being Hepatitis B, Hepatitis C and Human Immunodeficiency Virus (HIV), although this is only a small sample of the diseases that can be acquired.

Are there pathogens other than those being blood borne? Yes, there several other ways that pathogens can be transmitted, such as respiratory pathogens that can be transmitted through the air and, consequently, are known as air borne pathogens. The transmission of a pathogen involves three steps, being #1: escape from the host, #2: travel to the new host and #3: infection of the new host. Therefore, in addition to the body fluids and byproducts related to blood borne pathogens, we need to recognize the importance of others, such as feces, nasal secretions, sputum, sweat, tears, urine and vomitus.

Overwhelming? To some, Yes! The good news is that you do not need to become an epidemiologist to prevent or control every pathogen. As long as you understand how pathogens can be transmitted and how they can be inactivated or killed, you will be able to take care of the problem. This is where decontamination comes into the picture.

What is decontamination? Decontamination is the freeing of a person or object from a contaminant that might be a chemical, biological, radiological or nuclear substance. This is where it gets confusing for most people we polled, as the word 'decontamination' triggers an immediate relationship to a hazardous material team. However, we need to get past that, as not every incident involving a biological substance will require deployment of a hazardous material team, although some incidents may eventually lead to that.

For our purposes, we are only going to address the biological part. What does 'biological' mean? Biological means something relating to biology or living organisms, such as pathogens. When I first defined a pathogen above, I mentioned that a pathogen is an infectious biological microorganism. We now understand 'biological,' but what about 'microorganism'? A microorganism is any organism that is too small to be viewed by the unaided eye, such as viruses, bacteria, protozoa and fungi. Therefore, we are dealing with something that cannot be seen without a microscope, which means that, unless you are able to recognize the symptoms of an infected or contaminated person, if they are even exhibiting any, you will not know that you are now face-to-face with one.

Wow!!! If we don't know that we are face-to-face with one, how do we manage it? I have great news for you. Let's take the lessons learned from standard precautions and apply them to EVERY PATIENT – EVERY TIME – EVERY DAY!!! If you treat everyone as being infected or contaminated, there is no need to hone your profiling skills. If we simply stop worrying about how to recognize a patient infected or contaminated by Ebola, HIV, Hepatitis, Tuberculosis or any of the other headline diseases and realize that there is a world of other pathogens that are most likely to inflict harm on us or our loved ones, such as Influenza, Rotavirus, E. coli, C. diff, MRSA, MERS, etc., perhaps we will then realize that a child with a fracture deserves the same attention as an elderly man from 'that' quintessential nursing home where it seems everyone is infected with something incredibly contagious. It is not only cleaning up after an infectious patient (and you assume that someone is actually going to warn you that they are infectious, right?)…it is also preventing a healthy patient from coming contact with a dangerous pathogen. If we don't clean up after the infectious patient, there is good probability that it will be passed on to the next. Therefore, if we clean and disinfect the same way after every patient, imagine the improvement in health.

This is where the appropriate use of personal protective equipment, body hygiene, uniform hygiene and the decontamination of our gear (stretchers, monitors, bags, stethoscope, etc.), transport assets (ambulances, fire engines, police cars, paratransit vans, etc.) and spaces (crew rooms, decon areas, locker rooms, dining rooms, etc.) comes into play. It is a system with each component dependent on the other. Implement and maintain good programs and policies for each and the system will work.

This is a good time to share my 'Mom Clean' story. Are you prepared for the moment that your mom stops by the squad with a couple of good friends with the very proud objective of showing them what it is that you do? Does the idea of showing them the back of your ambulance make you feel ill? If so, you have a problem. What if they brought lunch for everyone and they are intent to enjoy that meal in the back of your ambulance? How does that vision make you feel? If it makes you sick to your stomach…good. Now imagine that same scenario and not feeling the anxiety. Either you are already implementing a proven Gold Star decontamination program or you may be a jackass that really needs to reconsider your future in public health.

Now that I have provided the background that led to us getting involved, I will begin outlining our program to instill awareness of the problem and modify our habits to combat it. On that note, I want to tell you that we are committed to working with all of the publishers to update all of the curriculum to include adequate lessons for infection prevention and control. It is great that we have focused on the importance of washing our hands and having a tidy uniform, but we know that we can do much better.

We took on a challenge to improve the first responder's ability to manage pathogens in the prehospital public health environment. Commitment to this challenge led us down many roads to determine what was necessary to manage the pathogens and whether the identified practices were being employed. Again, we determined that, for the most part, prehospital caregivers and other first responders lacked the necessary training to know how to manage pathogens and, most troubling, understand the importance of a good infection prevention and control program. Beyond that, we learned that extremely effective programs were utilized in food handling facilities, clean rooms and operating theaters, but, most likely due to an absence of regulations and/or appropriate oversight, these programs were essentially absent from prehospital public health. Prior to the Ebola Virus outbreak, many of these programs were unknown to prehospital public health and, sadly, following the outbreak's dematerialization, most of what was learned was placed into a dark filing cabinet to wait until the next scare. This is unacceptable, as it is time that we realize that infection prevention and control practices are designed for routine application and not intended to be recorded in a binder for reference when the federal government tells us that we need to implement our biodefense strategy. The best defense strategies are proactive with the ability to react instantaneously.

At this time, a proactive approach to biodefense is very counterintuitive to our current philosophy of reacting to known or suspected infectious disease, rather than employing practical infection prevention and control practices, as mandated by standard precautions that we must follow – treating every contact as a potentially infectious one – considering everybody as being contagious or completely unable to defend themselves against a contagion. Again, this is something that we must all adhere to – EVERY PATIENT – EVERY TIME – EVERY DAY – not just when we receive an alert from the hospital that the patient we transported two days ago has been diagnosed with an extremely contagious disease. What about every patient that was transported subsequently?

I mentioned food handling facilities, but I did not provide an opportunity for you to really think about why that might be important to us. Can you recall any instances where a restaurant chain has been detrimentally affected by seemingly ineffective practices in a food handling facility somewhere in its source pipeline? What impact did this have on that chain? Reputation damage? Fortunately, we do not hear this type of news very frequently. Why is that? Food handling facilities employ very aggressive proactive strategies, as not doing so will put them on a fast track to ruin.

Once we learned that, the next step was to learn whether prehospital public health was ready to adopt the proven practices employed by the food safety industry. Unfortunately, we learned that, although there is an appreciation for the issue, it is very easy for prehospital public health to provide a convenient list of reasons for why the issue can never be resolved, as the effort to achieve resolution is not practical. Simply put, they feel that they don't have the time to stop and deal with it. Not enough time available to deal with the issue? How can that be? How long does it take?

Anyone who has taken the time to read a label of a disinfectant can tell you that its effectiveness takes time to achieve. The surface typically requires manual physical cleaning first and then the decontamination agent must be applied to the surface in adequate quantities to enable it to have sufficient access to the surface for the required amount of time (Right chemical + Right amount of chemical + Right amount of chemical for the right amount of time). The required amount of time is known as contact time or dwell time. I will use dwell time for this memo. In most cases, the dwell time is ten to twenty minutes. If you consider that manual physical cleaning, alone, will take time, you quickly realize that you need more time to achieve the task than is likely allotted. Of the people we polled, most will tell you that they seldom, if ever, follow the instructions and, even if they took time to read the instructions, the required dwell time is simply inconvenient and, therefore, will not be obeyed.

If we know that we need to decontaminate (e.g., sanitize, disinfect or sterilize) our surfaces, why is the time not worth it? Is time really money? Let's consider training and policies. Ten minutes! Prehospital public health providers are routinely told that we need to be in and out in ten minutes. We need to assess the patient and get them loaded in ten minutes. We need to get them transferred to definitive care in ten minutes. We need to drop off the patient and get back in service within ten minutes. Where did this come from? Regardless of where it came from, we seriously need to reconsider it and conduct serious time studies to understand the reality of our time constraints.

As discussed above, if, on average, cleaning requires X minutes to achieve and a disinfectant requires Y minutes of dwell time, what is the value of X + Y? That value must be budgeted into the care plan and must be protected at all costs. Truth is, if this doesn't happen, failure to do so will cost you money. If good hygiene and the welfare of your patients, staff and family are not good enough reasons, perhaps risk mitigation will be convincing. What is the cost of an infection that can be traced back to your care, even if it is extremely unlikely? Why assume the risk? Why wait until an event happens before making a firm commitment to doing the right thing and championing the necessary organizational culture change? You will enjoy knowing that you can stand firmly and tell any attorney that your crews follow the same decontamination procedure – for every patient encounter - regardless of how ridiculous it might seem to some. You own it and they follow in your footsteps – each and every time.

Back to the adoption of best practices employed by the food handling facilities and clean rooms. I already mentioned regulations and oversight. They can be incredible influencing factors when it comes to change, right? Of course they are. The good ole dangle a scrumptious carrot or the carry a big threatening stick philosophies, for example. Honestly, I will be extremely disheartened if it comes to that. We are in a profession, whether volunteer or career, or some creative concoction of the two, that enables us to help others and, in fact, in most cases, aren't we gratefully duty bound? I think so. I can almost accept the need for a carrot or big stick approach

when it comes to industries established for the sole purpose of making a profit, because, face it, time is money, right? However, that being said, let's consider the consequences for taking short cuts in those industries. Reputations destroyed – beyond repair? Bankruptcy? Death of customer(s)? OK, bad example. No…, actually that is a perfect example! Just like non-healthcare businesses, consumers, whether customer, client, patient or resident, depend on us to provide the best service or product possible. They depend on us to make the best decisions on their behalf. When it comes to patients, in many cases, they are unable to advocate for themselves, so they have no choice, except to trust us with their well-being and place their lives in our hands without hesitation.

You wouldn't tolerate a filthy hotel room, so why would we allow ourselves to tolerate a disgusting patient care area?

Imagine what would happen if we learned that an operating room was not properly turned over after a surgical procedure. What if the hospital administrators reported that they just don't have time to worry about these things? Would we tolerate that? Of course not!

Remember what I said about a microorganism! What may be the most harmful component of your patient care area is the one you cannot see.

It all starts with 'the' clean. If you aren't willing or capable of getting on your hands and knees to scrub your patient care areas, you really need to think about that and determine a solution to get that done on a routine ongoing basis. The space must be free of all visible organic or inorganic matter, such as gum, road tar, blood, gauze pads, IV kit wrappers, fungus, heroin packets, fake eyelashes, etc. This includes the floor, walls, top/sides/bottom of all seats (bench, Captain's, driver's, passengers') all seatbelts and safety harnesses, ceilings, doors, door handles, radios, monitors, bags, top/sides/bottom of stretcher mattress, top/sides/bottom of stretcher rails, oxygen cylinder flow adjustments, cabinets, etc., etc., etc. If you can't achieve this, don't bother reading any further, as it doesn't matter what decontamination solution you use…it won't be effective. You can't simply spray Lysol on a dirty dish and consider it clean for the next guest!!!!

Chemical decontamination or ultraviolet decontamination? As we did our research, we narrowed our candidates to those two classes. Chemical gave us a bad taste in our mouth and ultraviolet, in its current form, had too many limitations. However, once we learned more about the chemical options, we learned that there are good chemicals and bad chemicals…those that are manmade and those borne by nature. Thus, we chose chemical with a commitment to continue exploring ultraviolet.

If it is so good, why hasn't it been introduced to prehospital public health? We ultimately reduced our search all the way down to Actril, which is peroxyacetic (peracetic) acid with a little touch of hydrogen peroxide and acetic acid to keep the reaction going. Actril became the obvious choice when we confirmed the claims of being able to achieve sterilization while also being environmentally-friendly and residue-free or requiring no wiping of the surfaces after the decontamination agent has been deployed. Some companies have referred to this as 'No Touch,' but we do not agree with that approach, as it seems to imply that 'If you use this system, you can skip the manual physical cleaning part,' which will never be the case. As for not being introduced to prehospital public health, that is not true. It has been in the industry for a while, but it has been unable to go mainstream, as there was no simple and affordable way to make it happen…until now.

But…what about sprays and wipes? As we spoke with infection control experts and epidemiologists, we learned that sprays are only as good as the instructions that are followed. Since we also learned that most people neglect to read and/or refuse to obey the label instructions, we understand what the experts were trying to tell us. In addition, there is the concern of incompatible products and the inappropriate use of personal protective equipment, when indicated. As for wipes, we learned that this category also includes users that do not read or obey label instructions, which leads to wipes being used while dry (they need to be soaked in the decontamination agent), the decontamination agent not being left on the surfaces for the required dwell time period and a snowplow effect, where the pathogens are being pushed or drug around the surface into piles resulting to a higher concentration of pathogenic load.

We knew that Actril could work quickly, aiming to introduce a program that could achieve a high level of disinfection within a very tight window of opportunity, so we had to develop a method to deploy it quickly and

effectively, without tilting the affordability scale in the wrong direction. This led to an expedited research and development program and dozens of deployment vehicle variants. In addition to being able to simply deploy the Actril solution, the vehicle had to be prepared for the challenges that it would face while combatting pathogens around the world in support of the global biodefense action plan, yet affordable to those experiencing financial anxieties. It had to be dependable, affordable, durable, relatively maintenance-free, operator-error-resistant, lightweight, portable and versatile.

Our efforts led to development of the AmbuStat fogger, which is built to resist the oxidative effects experienced by certain materials immersed in the Actril solution, using stainless steel components and a high efficiency filtration system to prevent the Actril solution from continuously drawing through the motor, to deploy the Actril solution at the prescribed droplet size, protecting critical electronic components and maximizing efficacy by optimizing successful travel and cling to the surfaces, to reduce operator fatigue by maintaining a light weight and making it highly portable for use in environments requiring ascent of multiple floors without the assistance of an elevator and to enable it to be used in austere conditions, such as environments where the power infrastructure has been interrupted and mobile generators must be used.

For larger spaces, the AmbuStat fogger's portability and versatility enables it to be deployed in multiples, simultaneously working together to reduce the amount of time required to treat the space. Add the turntable and it equalizes coverage of the surfaces and contributes to a decrease in treatment time.

This finally brings me to the point where I can address the 'Why AmbuStat?' part of this story.

You will recall that I mentioned, earlier in this memo, that the prehospital public health industry lacked an affordable option for employing proven chemical decontamination agents; however, I neglected to define affordable. Tens of thousands of dollars (some in excess of $50,000) is not affordable, especially when you are struggling to keep an ambulance on the street or a public health program afloat. It is very difficult to tell you, at least in a manner that you can appreciate, what we encountered to be able to introduce the program at a cost that enables you to fortify your biodefense plan without sacrificing critical components. Regardless, we were successful and are now able to give you only what you need, without having to charge you for bells and whistles that aren't essential to achieving your mission objective. Through the AmbuStat program, you get dependability, affordability, durability, relatively maintenance-free operation, operator-error-resistant functionality, light weight, portability and versatility.

As for our use of 'program,' we prefer to offer you a program, rather than a system, as when you make your commitment to invest in AmbuStat, you are becoming a member of a network with direct access to industry experts who will be walking alongside you to offer assistance in developing practices that will work best for your specific conditions. Through your adoption of our program, you will be contributing to the development of best practices that can be employed around the globe, leading to incredible advancements in the protection and improvement of public health and well-being. Together, we will teach the world that we can't sit and wait for the next newsworthy outbreak, as disabling and killing pathogens are already waging war on our soil. If we commit our resources to constructing an organized force with members assigned to every prehospital public health organization and dedicated patrols to keep everything in check, when a new pathogen threatens us, we will be able to focus on adjusting our strategy, rather than scrambling to build our forces from scratch. We can do this!

At this point, please take a moment to grab a fresh drink and enjoy our whiteboard presentation video by clicking on the following link: https://youtu.be/RsZZUpFCmAk.

Thank you for taking time to learn more about the AmbuStat program. I look forward to working with you.

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