DEFENSE THREAT REDUCTION AGENCY
8725 John J. Kingman Road, MS 6201
Ft. Belvoir, VA 22060-6201

EXECUTIVE PROJECT SUMMARY

PAEROSOL

BIOLOGICAL DECONTAMINATION OF HOSPITAL SUITES

DTRA RD-IST

Over 90,000 individuals die every year from "nosocomial infections," or hospital-acquired infections (HAIs). The Centers for Disease Control estimate that 1.7 million patients acquire HAIs annually with healthcare-associated costs between $5 and $11 billion. Many patients entering the hospital are already sick and are at risk from acquiring a secondary infection from contact with other patients, nurses, doctors, during surgery, catheterization, or from an inanimate surface like a telephone touch pad, nurses touch screens, bedrails, or privacy drapes, any of which may turn the visit to the hospital from routine to life threatening. Most common types of HAIs are urinary tract infections, followed by surgical site infections, bloodstream infections, and then pneumonia.

Military hospitals, dispensaries, barracks, mess halls, and troop transport systems provide a ready opportunity to contact and spread various bacteria and viruses. The spread of any disease within a military unit impacts readiness, performance, training, and all facets of military activity. Some HAIs are relatively easy to treat, some are drug resistant and some, like Methicillin-resistant Staphylococcus aureus (MRSA), can be life threatening to both patients and staff. Manual sanitation methods for disinfecting hospital rooms have demonstrated a limited effect for keeping the populations of bacteria and viruses in check for more than a day and have even resulted in increased sporulation of certain bacteria. What remains behind are enough colony forming units (CFUs) to give the populations the chance to roar back to life, just waiting for the next infectious opportunity. New safer methods are needed to enhance traditional decontamination procedures of hospital rooms, surgical suites, ICUs, and other facilities like school lunchrooms and athletic locker rooms where diseases can rapidly and easily spread. In addition to manual methods using Clorox®-like cleaners, gaseous or vaporous methods are now being tested in several hospital settings using hydrogen peroxides (GHP, VHP or HPV) or ozone. All provide the desired penetration of the space and are effective in neutralizing biological agents, but several of these methods are also mildly corrosive and require rigorous safety measures to ensure no one is exposed to the gases and vapors. An effective, non-corrosive, safe, and low-level manpower approach needs to be developed around this delivery method.

The Defense Threat Reduction Agency (DTRA), Technology Innovation Division of the Research Development Enterprise (RD-IST) has evaluated several candidate technologies that could not only defeat HAIs but could potentially decontaminate biological warfare (BW) organisms. One such technology employs a fog-like (i.e., aerosol) generating system using electrolyzed water containing various oxidative free-radical ions at very low concentrations as a disinfectant. As a liquid, it has the same disadvantages as conventional cleaning agents; but when aerosolized into a fog it kills bacteria and viruses, sterilizing all surfaces it comes in contact with or penetrates. This micro-aerosolization of electrolyzed water, named PAEROSOL, has been studied at the Institute for Highly Pure Biopreparation (IHPBP), one of Russia's former biological warfare research facilities, and at the Russian Research Institute of Influenza (RII). RII and IHPBP have demonstrated PAEROSOL efficacy against H1N1 and H1N5 viruses and a 6 $\log_{10}$ biological kill (complete kill) against a number of the HAIs such as various strains of Salmonellas, Bacillus spp. spores, Staphylococcus, Acinetobacter baumannii, and E. coli.

RD-IST funded Pacific Northwest National Laboratory to perform a series of studies in a US military hospital to validate the previously observed 6-$\log_{10}$ biological kill performance of PAEROSOL. The studies were conducted as an exploratory, observational, non-human subject trial at Madigan Army Medical Center (MAMC) against standard hospital borne pathogens. The trials were meant to validate the efficacy of PAEROSOL, to assess the impact of inadvertent exposure of PAEROSOL on standard hospital electronic equipment, and to optimize parameters for future deployment of PAEROSOL.

Tests were performed in a 2000ft^3 surgical suite containing equipment and furniture characteristic of a post-mortem room. Test equipment was positioned in the room including a pH meter, STEL electrolyzing device, humidity/temperature sensors, and peristaltic pump. MAMC provided inoculated test coupons of four different materials commonly found in the hospital setting (e.g., flooring tile, countertop material, privacy curtain fabric and carpet). A rigorous experimental design was established to include testing of approximately 350, 1" x 1" coupons of each material. All coupons were sterilized in a steam autoclave before use.

The trial included exposure of four microbial pathogens to PAEROSOL, representing Gram-negative, Gram-positive, and spore-forming species selected from the MAMC list of known HAIs. MAMC provided the test organisms so the specific strains were identical to those already known to be in the hospital: Klebsiella pneumoniae, Pseudomonas aeruginosa, Staphylococcus aureus, and Bacillus subtilis spores (as simulant of Clostridium difficile). One hundred microliters (100 µl) of bacterial inoculum in tryptic soy broth (which acted as an organic soil load) was applied to each coupon, providing an inoculum within the known range for various inanimate hospital surfaces of approximately $1x10^2$ CFU to $1x\ 10^5$ CFU/per coupon. The coupons were distributed across the room to provide a realistic scenario: Formica coupons were placed on the tables and coupons of curtain cloth were pinned to ribbons and positioned vertically. Each coupon was used only once and disposed of via approved methods. Additional experimental details including controls and normal survival characteristics of each microbial pathogen tested can be found in the body of the Final Report.

Following exposure, the microbes were extracted from the coupons, plated, grown, and enumerated to assess the viable CFU remaining on the coupons. The results validated the work performed at RII and IHPBP which reported 6 $\log_{10}$ reduction for similar organisms; PAEROSOL irreversibly eradicated below detection levels of 4-6 $\log_{10}$ for all microbial cells and spores that had been initially inoculated on the coupons of tile, Formica and fabric. The carpet was more difficult to penetrate with the PAEROSOL and the reduction in CFU count was depended on the microbe type and the depth into the fibers at which the inoculation took place. This resulted in a significant reduction in the range 2-4 $\log_{10}$.

The most effective protocol used 1.7 liters of pH-neutral electrolyzed solution to generate the PAEROSOL over 30 minutes during a total testing period of 3.5 hours. The aerosolized solution contained only table salt at a concentration of 2.5 – 5 g/L, which increases formation of various oxidative free radicals and ions. Safety precautions included vacating the room, shutting off the air handing system, and closing the door. The test left no waste other than a very light, dry, surface residue and posed no risk to those running the trail or other building occupants. Months of daily testing resulted in no observable deterioration of the PAEROSOL-exposed furniture and/or electronic equipment.

RD-IST recommends other organizations within DoD and DHS/CDC/EPA/NIH community interested in either HAI control or BW agent decontamination give PAEROSOL a closer review and evaluation. Further studies and work is clearly needed and warranted based on the results reported in the PNNL technical report, which can be obtained through the DTRA RD-IST COR, Mr. John C. Schaefer at DTRA (john.schaefer@dtra.mil).