Environmental Surfaces Decontamination Using ElectroWrap Novel Disinfection and Cleaning Systems

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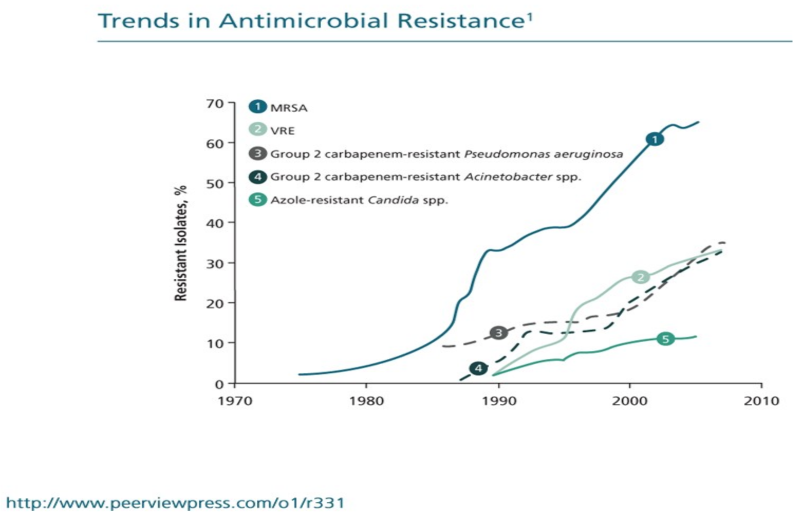
I. **Introduction**

The ElectroWrap disinfection control and cleaning systems are a patented combination of disinfectant solutions combined with a novel application method. Using a specialized electrostatic spraying applicator, the ElectroWrap solutions virtually "wrap around" onto all reachable surfaces, killing harmful pathogens, inhibiting re-growth for a prolonged period, while keeping surfaces clean. The ElectroWrap solutions are non-corrosive, odor reducing, and safe on all surfaces with a decades long track record for safety. The formulations include chemicals used routinely for environmental cleaning. Only about 10% of typical chemical concentrations are delivered in a micron sized spray using the science of electrostatics. The ElectroWrap disinfectant and cleaning systems have been successfully applied with validated results in hospitals, nursing facilities, day care centers, hotels, professional sports locker rooms and individual homes. Health care providers are currently grappling with an epidemic of Multi Drug Resistant Organisms (MDRO), a weak pipeline for new antibiotic drug development, environmental decontamination failures despite using current best EVS practices, and a growing population entering healthcare facilities. The Advisory Board Company estimates that nearly half of all hospitals lack antimicrobial stewardship programs. The ElectroWrap disinfection and cleaning systems offer an easy to use, innovative, cost effective, new standard of care opportunity for disease prevention in healthcare facilities.

II. **Healthcare associated infection epidemic**

Healthcare Associated Infections (HAIs) continue to be a major cause of patient morbidity and mortality. As the population ages, the number of people in hospitals, nursing homes, and other long term care facilities has increased significantly. With this growth in healthcare related admissions there has been an epidemic rise in HAIs. At any time about 1 in 20 hospital patients has a HAIs. According to the Center of Disease Control and Prevention (CDC), there are 2 million cases of HAIs caused by MDROs every year in the United States. Between 5-10% of all patients admitted to a hospital for extended care will contract a health care associated infection, and approximately 30,000 of these patients will die every year from preventable illness. This does not include those patients who contract a HAI while being treated for other conditions. According to the Journal of the American Medical Association, the cost per patient has been estimated to exceed $33K. The CDC lists HAIs as the fourth leading cause of death after heart disease, cancer and stroke. Nosocomial infections cost over $2,300 per incident and $4.5 billion annually in prolonged care and treatment. In the United States alone the estimated cost of HAI's is between $26-$33 billion annually.

Figure 1

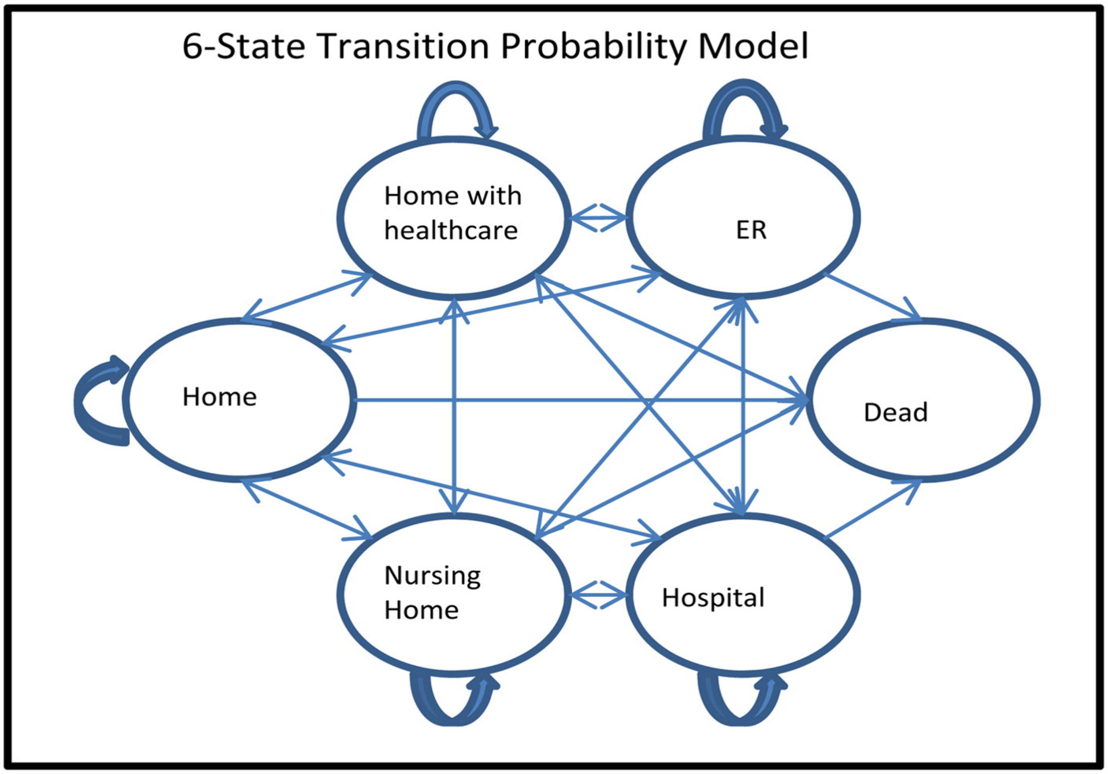


Pathogenic bacteria that are likely to cause harmful infection are becoming very resistant to antibiotic treatments in part because widespread antibiotic use gives a selective advantage to resistant strains (see figure 1). Health care facilities must work harder to combat HAIs caused by the spread of Multi Drug Resistant Organisms (MDRO) and viruses from one "handshake" facility to another as patients transfer from home to ER to hospital to nursing home (see fig 2). MDRO colonization and re-colonization of hospital units makes it increasingly difficult to contain epidemic clusters of infection. Resistant pathogens include:

--MRSA (methicillin resistant staphylococcus aureus)
--VRE (vancomycin resistant enterococcus)
--CRE (carbipenem resistant enterococcus)
--Acinetobacter baumanii
--Clostridium difficile (CDI)
--Pseudomonas aeruginosa
--Norovirus
--Rotavirus
--Influenza
--Candida

Although *viruses* are not technically MDROs, norovirus, rotaviruses, and influenza viruses spread rapidly creating epidemics in hospitals that add to morbidity and mortality among fragile patients. Newly emerging coronaviruses, such as SARS virus (Severe Acute Respiratory Syndrome), MERS virus (Middle Eastern Respiratory Syndrome) and the formerly well managed Ebola virus are far more serious epidemiologically. The recent Ebola virus epidemic in Africa showed how quickly serious pathogens can travel from one continent to another, much less from one "handshake" facility to another.

Figure 2



Dick AW et al. AJIC 43 (2015) 4—9

Efforts to control infection attack rates in hospitals include: better urinary catheter management, attention to sterile technique during central line insertion, ventilator associated pneumonia reduction, improved hand washing compliance, chlorhexidine bathing, antibiotic stewardship, and increased use of isolation rooms and personal protective equipment (PPE). Nonetheless, infection rates for *Clostridium difficile* and methicillin resistant *Staphylococcus aureus* (MRSA) continue to increase. In 2008 the U.S. Department of Health and Human Services (HHS) formed a Steering Committee to create a HAIs reduction action plan. The HHS plan singled out long term care facilities as a reservoir for *C difficile* pathogen among "handshake" facilities. As it has done with UTIs, Medicare will tie more healthcare facility reimbursements to so called preventable infections acquired during medical treatment. The HHS plan calls for a 25% reduction in MRSA infections and a 30% reduction in Clostridium difficile infections by the end of 2017. As of 2014, health care facilities in the United States are not on target to meet this goal.

III. Surface contamination as an environmental reservoir for pathogens

Best hand washing practices. Best hand washing practices are the most important component of a plan to reduce HAIs rates. Researchers estimate that 20-40% of HAIs result from cross contamination via hands. However, daily compliance with good hand washing practices is a regular struggle within healthcare facilities even though every healthcare worker knows that contaminated hands are a vector for disease transmission. Good enough hand washing rates vary from high (one nurse estimated she washes her hands 100 times per day!) to low (typically doctors and family members). Healthcare facilities have added easy to use "rub in/rub out" alcohol based hand sanitizer stations to ensure more frequent hand cleaning. Hand sanitizers do improve hand cleaning rates and can decrease transmission of most pathogens, with the notable exceptions of *C difficile* and norovirus.

However, even with good hand washing practices before and after *patient contact*, healthcare personnel are less likely to wash hands after contact with *environmental surfaces*, leading to persistent contamination of surfaces, equipment, and patients who touch those surfaces. Ulger, et al. (2009) sampled 200 healthcare workers cell phones and hands. They found 94.5% were contaminated. Most disturbingly, 13% carried MRSA bacteria. Finally, family members represents an infection vector to a facility as they pass in and out of isolation rooms without washing hands or using gowns and gloves, contaminating surfaces throughout a facility.

Best practices for cleaning of contaminated surfaces. Best cleaning practices can reduce the spread of bacterial biofilm colonies on many high touch surfaces. To accomplish this, good environmental disinfection and cleaning practices require:

-- ongoing staff education
-- proper selection of disinfection and cleaning agents
-- standardized application of those agents

Even with good choices for cleaning and disinfection agents, ongoing education of Environmental Service Workers (ESWs) regarding the proper application of disinfectants is necessary. For example, in an educational program for ESWs only 15% surveyed knew that a surface must stay wet with bleach solution for 8-10 minutes for disinfection of some pathogens (especially *C difficile*). Often, poor standardization of room cleaning arises from nothing more than the inconsistent use of *"elbow grease"*, which is necessary to scrub against biofilms. Biofilms are "housing colonies" for bacteria which allow a quick regrowth of bacterial colonies on surfaces. Using fluorescent markers and ATP assays to check the quality and consistency of daily and terminal room cleaning can improve quality control rates for uniformity and effectiveness. Some studies show a drop in cleaning efficacy from 90% to 60% when EVS supervisors change ATP monitoring sites. Effective bacterial load reduction in patient care environments cannot depend on how carefully and thoroughly a hospital's "best cleaner" does the job.

Proper selection of useable disinfection and cleaning agents is at least as important as choosing ones that clean or kill specific pathogens. Choosing cleaning and disinfection agents that are effective in several minutes, or ones that do not require large doses of *"elbow grease"* would make ESWs expenditure of time and energy more productive. Conversely, using the wrong disinfection and/or cleaning agents for the time and energy alloted to disinfection and cleaning is not productive in the end and endangers patient safety.

Finally, *standardized application* of a carefully chosen agent is crucial. Varied surfaces, the so called *"nooks and crannies"* found in rooms, hallways, nursing stations, and other special areas in a facility reduce the efficacy of disinfection and cleaning despite current best practices. We know that ESWs choose to focus on specific surfaces. These choices vary from worker to worker even under good supervision. The "nooks and crannies" of a hospital room, like those in household kitchen, are often left for "another day when I have more time" or for "another day when I can take that apart". In healthcare facilities, many surfaces are simply hard to clean, e.g. IV poles, monitors, any surface that is "underneath" requiring reaching or stooping, portable equipment, privacy curtains, curtains, vents, and bed rails among others.

A list of items and surfaces in a typical hospital room indicate how challenging it can be to achieve uniform environmental cleaning with cloths, sponges, mops, disinfectant wipes, and trigger sprayers:

- Bed rails
- Over bed table
- Infusion pumps
- IV poles/Hanging IV poles
- Nurse call box
- Monitor cables, EKG leads
- Vital signs equipment and monitors
- Telephone
- Countertops
- Toilets
- Sinks and surrounds

- Drains
- Soap dispenser
- Paper towel dispenser
- Computer keyboard and mouse
- Trash can
- Ventilation grill
- Light switches
- Curtains

Aside from daily and terminal cleaning of patient rooms, where adequate quality control of decontamination practices across varied surfaces is theoretically achievable day in and day out, *special environments* are far more challenging. For instance, a physical therapy gym (exercise equipment, pulleys, lifts, railings); a walker, wheelchair, and IV pole storage area; or an operating room (monitors, cables) have many "problem surfaces". Sports gyms may pose a greater threat for infection, especially viruses and MRSA, but hospital gyms are no less endangered from inadequate cleaning of its many *"nooks and crannies"*, surfaces that are difficult or impossible to treat manually.

Environmental reservoir. This may be an obvious question, but nonetheless important to ask given the high stakes involved for risks to time, money and patient safety: How do we know that the *best* cleaning and disinfection practices *fail* to decontaminate surfaces thoroughly, leaving an environmental reservoir of bacterial and viral pathogens (biofilms), thereby failing to prevent HAIs? A new system for quick, visual identification of specific pathogens or biofilms would answer the first part of the question. Research and development of such a tool is in progress. The second part of the question must be answered with good epidemiological studies.

The most convincing evidence for an inadequately cleaned environmental reservoir of pathogens causing indirect disease transmission comes from *"prior room occupancy"* studies. Researchers asked a simple question: "Do patients admitted to a room formerly occupied by an infected person have a greater risk for developing that same infection?" A summary of several studies calculated that, despite terminal room cleaning, new patients stood a 100-300% greater chance of acquiring the infection of a room's prior occupant. One researcher calculated the attack rate for *C difficile* was 4% without an infected prior occupant vs. 11% for an infected prior occupant.

Otter et al. (2013) reported anecdotally that "[When] six experts speaking at an environmental session [of an infection control conference] were asked to estimate the 'percentage of all *C difficile* transmission that is mediated directly, or indirectly, by contamination of the inanimate environment, the responses ranged from 25% to 75%."

In a full review of whether environmental surfaces serve as a reservoir for cross contamination, Hata (2013) found that there is compelling evidence of survival in environmental reservoirs for *C difficile*, Vancomycin-Resistant Enterococci (VRE), and Methicillin-Resistant *Staphylococcus Aureus* (MRSA). He also found that there is evidence for probable survival in environmental reservoirs among norovirus, influenza virus, Severe Acute Respiratory Syndrome-Associated Coronavirus (SARS), and *Candida* species.

In summary, Otter et al. (2013) state emphatically that:

"There is now *compelling evidence* from modeling of transmission routes, microbiologic studies, observational epidemiology studies, intervention studies, and outbreak reports that contaminated surfaces contribute to the transmission of hospital pathogens. [More] needs to be done to improve surface decontamination."

IV. New environmental disinfection systems.

Clearly, infection control managers require new strategies to attack MDROs and to achieve more thorough cleaning and decontamination across all the varied surfaces in their facilities. As above, the best cleaning and disinfection strategies might break the cycle of contamination and HAIs from environmental reservoirs if healthcare facilities could focus on solving the "elbow grease" and "nooks and crannies" problems with agents that are effective within the reasonable time allowed.

New cleaning and disinfectant agents that are not as noxious as high dose chlorine products would be helpful. Improved hydrogen peroxide in triggers sprayers is promising in that regard. Or, ESWs could use their time and energy focusing on the highest environmental reservoir risk areas. Curtis et al (2013) suggests:

-- improved terminal cleaning of isolation rooms
-- daily disinfection of high-touch surfaces
-- disinfection of portable equipment
-- improved cleaning of non-isolation rooms

New cleaning and disinfection systems. While these strategies may help, a new *system* that corrects the unintended deficiencies of best cleaning and disinfection practices would be best. An ideal new system should meet two goals: use lower doses of cleaning or disinfection agents AND solve the application inconsistencies caused by the "elbow grease" and "nooks and crannies" problems. Formally stated:

"New cleaning and disinfection *systems* should use the least toxic chemicals at the lowest dose to supplement best cleaning practices in order to *standardize* surface decontamination and therefore *minimize* transfer of harmful pathogens from *widely varied* surfaces that serve as an *environmental reservoir* for bacterial or viral infection."

Three known systems are available and research points to significant reductions in the proportion of surfaces contaminated by MDROs with decreased disease transmission rates. New generation disinfection systems include: semi-automated UV light systems and vaporized hydrogen peroxide generators, or non-automated electrostatic spray systems. All three of these systems offer a better chance to achieve the two goals stated above: less chemical used and standardized application. Healthcare facility managers have choices to make among these three very different disinfection systems. But how should they evaluate the choices?

Facilities managers could begin with this question: What are the criteria for an *ideal* disinfection or cleaning system? Rutala (2014) lists the following six criteria for an ideal system:

1) Kills a broad array of gram positive, gram negative bacteria, viruses, molds and mildew
2) Easy to use and dispense
3) Has an affordable startup cost
4) Has a simple learning curve and training program
5) Provides complete coverage of a wide array of surfaces
6) Is fast acting and effective for an extended period of time

In the chart below there is a simplified comparison among these three new systems. While any of the three systems could improve surface decontamination rates and cleaning standardization, the ElectroWrap disinfection system meets *all* the criteria of an *ideal* disinfection system.

	UV system	***Hydrogen peroxide vaporizer***	***ElectroWrap/IsoKlean disinfection system***
Seal off Room	No	Yes Tape off vents	No
Easy to use	No	No	Yes
Affordable start up	No	No	Yes
Simple learning curve	No	No	Yes
Wide array of surfaces	No, line of sight surfaces only, rearrange furniture, specialized paint	Yes	Yes

Odor Neutralizer	No	No	Yes
Extended efficacy	Yes for surfaces treated	Yes	Yes

Obviously, a new cleaning and disinfection system should, of course, do its job. It should clean all of the surfaces in a vulnerable environment. And when used as a disinfectant, it should kill a broad array of pathogens with enough suppression of re-growth for a long enough time so that re-application does not inconvenience patients and staff. But without question it must be *practical,* i.e. -- *easy to use* so that many ESWs, not just the best, can apply it effectively and quickly, where and when needed. Otherwise, even a good disinfection system will be like expensive exercise equipment—rarely used and eventually stored in the basement.

V. The ElectroWrap System

The new ElectroWrap system combines *patented chemical solutions* and an *electrostatic spray application*. An electrostatic spray application minimizes the amount of chemicals used by applying "just enough" solution in "just the right places". It cures the failures of not enough "elbow grease" and "nooks and crannies". In a *few seconds*, the ElectroWrap electrostatic spray method distributes a micron sized droplet solution into even the most geometrically complex spaces making it possible to achieve an essential standard of care: *"complete coverage of a wide array of surfaces".*

X-100 EPA approved disinfectant

A. The X-100 solution is a specially formulated, patented 4th generation quaternary ammonium salts solution approved by the EPA for use as a hospital disinfectant:

- effective on a broad array of gram positive and gram negative bacteria, viruses, molds and mildew including ESKAPE pathogens (see below).
- patented chemistry with a decades long track record for safety
- effective in the presence of organic material
- non-corrosive, safe on fabrics and other materials
- safe to handle while mixing from concentrate to Ready to Use
- safe to apply, ESWs need a face mask to prevent inhalation of mist while it is airborne and light, goggles, and long sleeved protective clothing or standard hospital "blue gowns"
- neutralizes many odors

B. Electrostatic spray application

- delivers a 40 micron negatively charged droplet spray that clings to all grounded surfaces ("nooks and crannies")
- ***30 – 60 seconds*** spray time for an average hospital room ("elbow grease")
- not necessary to tape off air vents or to seal a room
- dries on contact
- only requires a few minutes to allow the spray mist to settle before a room can be used safely
- easy to use, ESW training averages 1 to 2 hours

VI. Efficacy studies

How effectively does the X-100 hospital disinfectant solution kill pathogens?

1. Partial list of pathogenic bacteria and viruses killed in studies filed with the EPA
    - o Staphylococcus aureus
    - o Methicillin resistant Staphylococcus aureus (MRSA)
    - o Clostridium difficile
    - o Acinetobacter baumanni
    - o Escherichia coli (enterococcus)
    - o Carbipenem resistant enterococcus
    - o Vancomycin intermediate resistant Staphylococcus aureus (VISA)
    - o Klebsiella pneumoniae
    - o Mycobacterium tuberculosis var: bovis (BCG)
    - o Pseudomonas aeruginosa
    - o Streptococcus faecalis
    - o Streptococcus pyogenes (Clinical-Flesh Eating strain)
    - o Streptococcus salivarius Salmonella enterica
    - o Brevibacterium ammoniagenes
    - o Enterobacter aerogenes
    - o Listeria monocytogenes
    - o Mycoplasma gallisepticum
    - o Salmonella schottmuelleri • Shigella dysenteriae
    - o Viruses:
        - Norovirus
        - SARS virus
        - Influenzavirus A2
        - Hepatitis B
        - Hepatitis C

- HIV

- Fungi:
  - Trichophyton mentagrophytes
  - Aspergillus niger

2. Laboratory studies filed with the EPA show *very* significant kill rates for the ESKAPE pathogens important in hospital infection control:
   - *Staphylococcus aureus*
   - *Salmonella enterica*
   - *Pseudomonas aeruginosa*
   - *Escherichia coli (enterococcus)*

VI. Conclusion

Advances in disinfectant and cleaning *systems* are a critical leap forward in controlling the environmental reservoir of pathogenic surface contaminants in healthcare facilities. The ElectroWrap system significantly controls three key metrics for EVS departments in those facilities: time, money, and efficacy while providing a safer environment for both patients and hospital workers. The ElectroWrap system combines well known chemicals in new ways, at lower doses, with a novel, very rapid electrostatic application method that establishes it as the *new standard of care*.

Notes

1. Septimus, EJ, “Confronting the mounting challenge of gram-negative drug resistant nosocomial infections in the acute care setting”, Peer Review Press, April 2, 2014
2. Hota, B., “Contamination, disinfection, and cross-colonization: are hospital surfaces reservoirs for nosocomial infection?” CID 2004:39 (15 October) Healthcare Epidemiology
3. Otter et al., Am J of Infection Control, Vol. 41, Issue 5, Supplement, pp. S6-S11, May 2013
4. Curtis et al., Am J of Infection Control, Vol. 41, Issue 5, Supplement, pp. S12-19, May 2013
5. Rutala WA, “Selection of the ideal disinfectant”, (from Infection Control Report, 2/21/14, www.disinfectionandsterilization.org)
6. Advisory Board Council – Web: http://www.advisory.com/daily-briefing/2015/05/01/hospitals-not-doing-enough-to-stop-superbugs#.VUORqIoH0IE.email